UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters Products Liability Litigation	MD-15-02641-PHX-DGC
	Phoenix, Arizona
	March 29, 2018
Sherr-Una Booker, an individual,	
Plaintiff,	
v.	CV-16-00474-PHX-DGC
C.R. Bard, Inc., a New Jersey corporation; and Bard Peripheral Vascular, Inc., an Arizona corporation,	
Defendants.	

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 11

(Pages 2439 - 2570)

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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

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I N D E X

10:01:31 **P R O C E E D I N G S**

(Proceedings resumed in open court outside the presence of the jury.)

08:47:04 THE COURT: Thank you. Please be seated.

Morning, everybody.

EVERYBODY: Morning, Your Honor.

08:47:28 THE COURT: Let me mention a couple of things about verdict forms and jury instructions and we'll have those in to you shortly.

I went back after our discussion yesterday and looked at the instruction on comparative fault, which is instruction number 18, and specifically whether the word "usually" should be in paragraph C, which was a question raised by plaintiff's

08:47:49 counsel.

And after we went back and looked at the Georgia cases we decided it should not be in there even though it's in the model instruction, and this is the reason:

The Georgia Supreme Court in the *Beach* case, *Beach versus Lipham* said that "usually" should come of that

08:48:11 instruction. It didn't happen. I don't know why the Georgia Bar doesn't follow that direction from the Georgia Supreme Court. But it didn't happen.

And I think the reason it didn't happen is because

08:48:25 there's a line of cases and, in fact, a different model

instruction that says there are some cases where the malpractice is so obvious that you don't need an expert. Like the doctor, you know, amputates the wrong limb, or something like that. And so I think "usually" was left in because of those kinds of cases.

But this isn't that kind of case. In this kind of a case where it's not obvious to a layperson, it seems to me *Beach versus Lipham* controls, and you do need an expert witness.

So we've taken "usually" out of paragraph C and instruction 18. And that will be handed to you shortly. I think copies are being made.

The second thing we did in light of my ruling last night was to take the intervening cause instruction and broaden it to include Dr. Bard and the radiologists, so it's just the same instruction but reworded in light of the fact that I denied the motion for judgment as a matter of law on intervening cause with respect to the radiologists.

And we're going to hand you copies of instruction 18 and 20.

The third thing we did is we reworked the verdict form yet again.

And, Jeff, if you could hand those out now.

We eliminated Section C in the form it was last night where we're asking the jury to specify an amount related to an

08:50:00 intervening cause, because I was persuaded by plaintiff's argument that that could be confusing and could result in a double deduction.

What we did instead is add a new section at the end 08:50:12 that asks two interrogatories of the jury about what they did when they found liability. Namely, if you ruled completely in favor of Bard was that based on a finding of superseding cause; and secondly, if you awarded damages, was it reduced by a finding of superseding cause.

08:50:35 That way we'll know whether or not they factored it in, which could eliminate an appeal or posttrial motion. But we're not interfering with their deliberation on proximate cause, as the other section did.

So look over that, if you would. We can comment on 08:50:53 that during a break or even at the close of argument before we actually hand it to the jury.

There is a paragraph at the end of part A that gives the jury instructions, which says: If you find in favor of Bard then you have to answer B, which is the damages amount; 08:51:11 C, which is comparative fault; and D, which is punitive damages. And the second question in E, which is, Did you reduce the damages by any superseding cause.

It also says, If you found in favor of Bard, you don't answer B, C, or D, you just answer the first question in 08:51:31 E, which is, was it based on superseding cause.

08:51:35 So look over that. Or have somebody look it over. And we can talk about that during a break or the at the end of the arguments.

The other thing I wanted to mention, because I was 08:51:47 too tired last night to write it, in the order I said that I was denying the motion for a judgment as a matter of law with respect to Dr. Kang because I found there was enough evidence to go to the jury on the first and second elements of superseding cause.

08:52:05 The reason I reached that conclusion was we went back and looked at Georgia law to see if we could find any clarification on what does or does not constitute a trigger, the second element, or does or does not constitute foreseeability for purposes of the first element, and there's 08:52:23 nothing we could find. No case law. We traced it back to the restatement and we couldn't find anything.

And in light of the fact that Georgia law says I can only grant judgment as a matter of law if it is clear, plain, palpable, and undisputed, my conclusion is when the standard 08:52:42 hasn't been precisely characterized, I can't say that a jury couldn't find those elements based on the evidence that's been presented, and I ought not to enter judgment as a matter of law.

So that was the reasoning behind the first part of 08:52:55 the order that I entered last night.

08:52:57 Let me mention a couple of other things.

We've given the plaintiffs an hour and 15 minutes for closing.

Mr. Lopez or Mr. O'Connor, are you going to want to 08:53:08 reserve any of that for rebuttal argument?

MR. LOPEZ: Yes, Your Honor.

THE COURT: Do you want me to keep track and tell you when you've got five minutes left on the amount you want to take, or are you going to take care of that?

08:53:19 MR. LOPEZ: What do you think? Are we going to take care of this?

(Counsel confer.)

MR. LOPEZ: I want to leave him at least 20 minutes, so --

08:53:25 THE COURT: Well, do you want me to tell you, then, when you're at 50 minutes and when you're at 55 minutes?

MR. LOPEZ: How about when I'm at 30 and 45.

THE COURT: 30 and 45. Okay. I'll do that.

MR. LOPEZ: Thank you.

08:53:46 THE COURT: Two other things I wanted to mention. Please remember that our Local Rule 39.2(b) prohibits you from contacting jurors after the trial unless you go through me.

And, finally, what I would like to do this afternoon after the lunch break, I think we'll get the arguments done 08:54:04 even if we go into the lunch hour, for the odd bureaucratic

reason we can't by the jurors lunch unless they have the case to deliberate. I would like to finish argument so we can buy them lunch and they can start deliberation. But I would like to then come back after lunch and talk about scheduling for the Jones trial, when we're going to get certain motions in, when we're going to get depo designations in, things like that, so we get that all done while you're here.

All right. Plaintiff, do you have matters to raise before we --

Sorry, just one second.

(The Court and the judicial assistant confer.)

MR. STOLLER: Your Honor?

THE COURT: Hold on just a second.

Okay. Yes?

MR. STOLLER: I think you addressed on the instructions everything except for the plaintiff's renewed request on the limiting instruction for the FDA.

THE COURT: Thanks for mentioning that. I concluded not to give that because I continue to believe the operation of 510(k) and clearance is clear from what's been presented at the trial.

MR. STOLLER: And it's your intention for us to talk about the verdict form at the break or over the noon hour?

THE COURT: Yeah. I want you to have time to read through it and make sure I haven't made errors along the way.

08:55:17 MR. STOLLER: Thank you.
THE COURT: So let's not do that right now.
Anything else from plaintiff?
How about from defendants?
08:55:22 MR. NORTH: Nothing, Your Honor.
THE COURT: Okay. Let me just make sure I've got the right version here.
Okay.
Traci, let's see if the jury is ready.
08:55:37 (The jury entered the courtroom at 8:55.)
THE COURT: Please be seated.
Good morning, ladies and gentlemen.
JURORS: Good morning.
THE COURT: Thank you for being here this morning.
08:59:17 As we indicated last evening, we're going to start with jury instructions, and then we will have the closing arguments of the parties.
I will mention that Mr. Lopez has asked that I tell him when he reaches 30 and 45 minutes just so he can time it.
08:59:32 It's not that I'm trying to keep him on a leash, but he's asked me to help him on that.
And then after we finish the closing arguments, we'll give the case to you for deliberation.
I think what I'd like to do, because I think the
08:59:48 timing will go work, is finish all the arguments before lunch,

even if it pushes a little bit into the noon hour. That allows us to buy lunch for you, and you can just order lunch from the jury room and begin deliberation, and we don't have to break for an hour and come back and lose that hour of deliberation.

So if it's okay with you, we'll go, with a break, until we finish the arguments so you can then begin your deliberation.

Members of the jury, now that you have heard all of the evidence, it is my duty to instruct you on the law that applies to this case.

A copy of these instructions will be sent to the jury room for you to consult during your deliberations.

It is your duty to find the facts from all the evidence in the case. To those facts you will apply the law as I give it to you. You must follow the law as I give it to you whether you agree with it or not. And you must not be influenced by any personal likes or dislikes, opinions, prejudices, or sympathy. That means that you must decide the case solely on the evidence before you. You will recall that you took an oath to do so.

Please do not read into these instructions or anything that I may have said or done as indicating that I have an opinion regarding the evidence or what your verdict should be.

09:01:13 Although there are two defendants in this case, C.R. Bard, Inc., and Bard Peripheral Vascular, Inc., you should decide the case as to the two defendants jointly. As a result, in these instructions and in the verdict form we will 09:01:33 refer to defendants collectively as "Bard." Unless otherwise stated, the instructions apply to both Bard and Ms. Booker.

The evidence you are to consider in deciding what the facts are consist of the sworn testimony of the witnesses, the exhibits that are admitted into evidence, any facts to which 09:01:56 the lawyers have agreed, and any facts that I have instructed you to accept as proved. And the only facts on which I've given that instruction is the matters that were agreed to that I read you right at the beginning of the case or that were read by the parties before each of the deposition excerpts 09:02:16 were played.

In reaching your verdict you may consider only the testimony of the witnesses, the exhibits received into evidence, and the facts to which the parties have agreed.

Certain things are not evidence and you may not 09:02:32 consider them in deciding what the facts are. I will list them for you:

First, arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they have said in their opening statements, may say in their closing 09:02:47 arguments, and at other times, is intended to help you

09:02:52 interpret the evidence, but it is not evidence. If the facts as you remember them differ from the way the lawyers have stated them, your memory of the facts controls.

Second, questions and objections by lawyers are not 09:03:06 evidence. Attorneys have a duty to their clients to object when they believe a question is improper under the rules of evidence. You should not be influenced by the objections or by the Court's ruling on it.

Third, testimony that is excluded or stricken or that 09:03:24 I have instructed you to disregard is not evidence and must not be considered.

In addition, some evidence is received only for a limited purpose. When I have instructed you or instruct you to consider certain evidence only for a limited purpose, you 09:03:40 must do so and you may not consider that evidence for any other purpose.

Fourth, anything you may have seen or heard when the Court was not in session is not evidence. You are to decide the case solely on the evidence received during the trial.

09:04:00 Some exhibits admitted into evidence have been partially redacted, which means that certain contents of the exhibits have been blacked out or whited out. The parties and I have redacted information that is not properly admitted as evidence. You may give the unredacted information in any 09:04:21 exhibit whatever weight you choose, but you must disregard the

09:04:26 redacted information and must not speculate about what it might say.

You have heard testimony from a number of witnesses who testified to opinions and the reasons for their opinions. 09:04:40 This opinion testimony is allowed because of the education or experience of those witnesses.

Such opinion testimony should be judged just like any other testimony. You may accept it or reject it and give it as much weight as you think it deserves, considering the 09:04:59 witness's education and experience, the reasons given for the opinion, and all of the other evidence in the case.

Federal law prohibits current FDA employees from testifying in court regarding any function of the FDA, and prohibits current and former FDA employees from testifying 09:05:24 about information acquired in the discharge of their official duties, without authorization from the commissioner of the FDA. As a result, neither side in this case was able to present testimony from current FDA employees or former FDA employees regarding the discharge of their duties related to 09:05:47 this case.

Certain charts and summaries not admitted into evidence have been shown to you in order to help you explain the evidence in the case. These have been referred to as "demonstrative exhibits." The demonstrative exhibits are only 09:06:07 as good as the underlying evidence that supports them. You

09:06:11 should therefore give them only such weight as you think the underlying evidence deserves.

Certain charts and summaries have been admitted into evidence to illustrate information brought out in trial. 09:06:27 Charts and summaries are only as good as the testimony or other admitted evidence that supports them. You should, therefore, give these exhibits only such weight as you think the underlying evidence deserves.

All parties are equal before the law, and a 09:06:49 corporation is entitled to the same fair and conscientious consideration by you as any party.

Under the law, a corporation is considered to be a person. It can only act through its employees, agents, directors, or officers. Therefore, a corporation is 09:07:10 responsible for the acts of its employees, agents, directors, and officers performed within the scope of authority.

Ms. Booker asserts four claims against Bard. First, strict product liability based on design defect; second, strict product liability based on failure to warn; third, 09:07:40 negligent design; and, fourth, negligent failure to warn.

I will instruct you on the law that applies to each of these claims. You should consider each claim separately.

Before I give you instructions about Ms. Booker's specific claims, let me give you a few instructions that will 09:08:02 apply to all of the claims.

09:08:05 When a party has the burden of proving any claim or affirmative defense by a preponderance of the evidence, it means that you must be persuaded by the evidence that the claim or affirmative defense is more probably true than not 09:08:20 true. You should base your decision on all of the evidence regardless of which party presented it.

Some instructions will state that you must find that an event or condition or action was the proximate cause of Ms. Booker's injury. Proximate cause means that cause which, 09:08:44 in a natural and continuous sequence, produces an event, and without which cause such event would not have occurred. Thus, when I use the expression "proximate cause," I mean a cause that, in the natural and ordinary course of events, produced Ms. Booker's injury.

09:09:06 In order to be a proximate cause, the act or omission complained of must be such that a person using ordinary care would have foreseen that the event or some similar event might reasonably result.

There may be more than one proximate cause of an 09:09:25 event. Thus, to prove proximate cause, Ms. Booker need not prove that an act or omission was the only cause or the last cause or the nearest cause. It is sufficient if it combines with another cause resulting in the injury. However, if an act or omission of any person not a party to the suit was the 09:09:48 sole proximate cause of an occurrence, then no act or omission

09:09:53 of any party could have been a proximate cause.

Ms. Booker contends that Bard is strictly liable because of a defective design of the G2 IVC filter. The manufacturer of a product that is sold as new property may be 09:10:15 liable to any person who is injured because of a defect in the product that existed at the time the manufacturer sold the product.

However, a manufacturer of a product is not an insurer, and the fact that a product may cause an injury does 09:10:31 not necessarily make the manufacturer liable.

To recover damages for strict product liability based on a design defect, Ms. Booker must establish the following three elements by a preponderance of the evidence:

First, the product was defectively designed;

09:10:52 Second, the design defect existed at the time the product left the control of Bard;

And, third, the design defect in the product was a proximate cause of Ms. Booker's injury.

There is not a single general way to define what 09:11:11 constitutes a design defect in a product. Whether or not a product is defective is a question of fact to be determined by you, the jury, based on the instructions that I will give you and the evidence that has been received during the trial.

Although Bard is not required to ensure that a 09:11:30 product design is incapable of producing injury, it has a duty

09:11:35 to exercise reasonable care in choosing the design for a product.

To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a 09:11:48 product design against the utility or benefits of that product design. You must decide whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including the following factors:

09:12:07 The usefulness of the product;

The severity of danger posed by the design, the likelihood of that danger, the avoidability of the danger considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and 09:12:27 common knowledge, or the expectation of danger;

The user's ability to avoid the danger;

The technology available when the product was manufactured;

The ability to eliminate the danger without impairing 09:12:45 the product's usefulness or making it too expensive;

The feasibility of spreading any increased cost through the product's price;

The appearance and aesthetic attractiveness of the product;

09:13:00 The product's utility for multiple uses;

09:13:03 The convenience and durability of the product;

Alternative designs of the product available to the manufacturer;

And the manufacturer's compliance with industry
09:13:13 standards or government regulations.

In determining whether a product was defectively designed, you may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized Ms. Booker's injury.

09:13:30 In determining the reasonableness of the product design chosen by Bard, you should consider:

The availability of an alternative design at the time Bard designed this product;

The level of safety from an alternative design
09:13:45 compared to the actual design;

The feasibility of an alternative design considering the market and technology at the time the product was designed;

The economic feasibility of an alternative design;

09:14:00 The effect an alternative design would have on the product's appearance and utility for multiple purposes;

And any adverse effects on Bard or the product from using an alternative design.

In determining whether a product was defective, you
09:14:19 may consider proof of a manufacturer's compliance with federal

09:14:22 or state safety and non-safety standards or regulations and industry-wide customs, practices, or design standards.

Compliance with such standards or regulations is a factor to consider in deciding whether the product design 09:14:41 selected was reasonable, considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect.

In deciding whether the design of the G2 filter was 09:14:58 defective, you may also consider whether the FDA instituted regulatory action with respect to the G2 filter. However, a product may be defective even if the FDA institutes no regulatory action.

If you decide that the risk of harm in the product's 09:15:18 design outweighs the utility of that particular design, then the manufacturer exposed the consumer to greater risk of danger than the manufacturer should have in using that product design and the product is defective.

If, after balancing the risks and utility of the 09:15:36 product, you find by a preponderance of the evidence that the product suffered from a design defect that proximately caused Ms. Booker's injury, then Ms. Booker is entitled to recover.

Ms. Booker contends that Bard is strictly liable because it failed to give adequate warnings regarding the G2 09:16:04 IVC filter.

09:16:07 The manufacturer of a product that is sold as new property may be liable to any person who is injured because of an inadequate warning with respect to the product that existed at the time the manufacturer sold the product. However, a 09:16:23 manufacturer of a product is not an insurer, and the fact that a product may cause an injury does not necessarily make the manufacturer liable.

The manufacturer of a medical device does not have a duty to warn the patient of the dangers involved with the 09:16:41 product, but, instead, has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer.

To recover damages for strict liability based on an inadequate warning, Ms. Booker must establish the following 09:17:00 three elements by a preponderance of the evidence:

First, the warning given with the product was inadequate;

Second, the inadequate warning existed at the time the product left the control of Bard;

09:17:16 And, third, the inadequate warning was a proximate cause of Ms. Booker's injury.

There is no single general way to define what constitutes an inadequate warning in a product. Whether or not a warning is inadequate is a question of fact to be 09:17:34 determined by you, the jury, based on the instructions that I

09:17:37 will give you and the evidence received during the trial.

Bard had a duty to give an adequate warning of known or reasonably foreseeable dangers arising from the use of the G2 IVC filter. Bard owes this duty to warn to all physicians 09:17:57 whom the manufacturer should reasonably foresee may use the product.

Bard's duty to warn may have been breached by, A, failing to provide an adequate warning of the G2 filter's potential dangers, or, B, failing to adequately communicate to 09:18:17 Ms. Booker's physicians the warning provided.

A manufacturer's duty to warn arises when the manufacturer knows or reasonably should know of the danger presented by the use of the product. Therefore, a manufacturer has a continuing duty to adequately warn of 09:18:38 defects in a product even after that product has left the control of the manufacturer.

You must decide whether adequate efforts were made by Bard to communicate all risks that were known or reasonably should have been known to Bard, to the physician who implanted 09:18:58 the G2 filter in Ms. Booker, and whether the warning that Bard communicated was adequate.

A product, however well or carefully made that is sold without an adequate warning of such danger may be said to be in a defective condition. If you find by a preponderance 09:19:17 of the evidence that Bard did not adequately warn when an

09:19:21 adequate warning should have been given, and that this inadequate warning proximately caused Ms. Booker's injury, then you may find the G2 filter to be defective and for that reason find that Ms. Booker is entitled to recover.

09:19:47 Ms. Booker claims that Bard was negligent in the design of the G2 IVC filter she received. To recover on this claim, Ms. Booker must prove by a preponderance of the evidence that:

One, Bard had a duty of reasonable care to

09:20:04 Ms. Booker;

Two, Bard breached that duty in the design of the G2 -- I'm sorry, of the G2 filter;

Three, the breach was a proximate cause of Ms. Booker's injury;

09:20:18 And, four, she suffered damages.

Reasonable care is that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Ms. Booker has failed to prove any one of the four

09:20:37 elements by a preponderance of the evidence, then you must find that Bard was not negligent in the design of the G2 filter she received.

Ms. Booker claims Bard was negligent in failing to warn about the risks of the G2 IVC filter she received. To

09:21:00 recover on this claim, Ms. Booker must prove by a

09:21:03 preponderance of the evidence that:

One, Bard had a duty of reasonable care to Ms. Booker;

Two, Bard breached that duty in the adequacy of the 09:21:13 warnings about the G2 filter;

Three, the breach was a proximate cause of her injury;

And, four, she suffered damages.

The reasonable care -- pardon me. Reasonable care is 09:21:27 that degree of care that is used by ordinarily careful manufacturers under the same or similar circumstances.

If Ms. Booker has failed to prove any one of the four elements by a preponderance of the evidence, then you must find that Bard was not negligent in failing to warn about the 09:21:46 risks of the G2 filter she received.

Bard contends that Ms. Booker's injuries were caused, in whole or in part, by the negligence of Dr. Sarwat Amer. Bard bears the burden of proving Dr. Amer's negligence by a preponderance of the evidence.

09:22:15 If you find that Ms. Booker is entitled to recover for her injury and you further find that Bard has shown that the damages sustained by Ms. Booker were caused in whole or in part by the negligence of Dr. Amer, you should consider the negligence of Dr. Amer, even though he is not a party to this 09:22:39 case. The verdict form will instruct you to assign a

09:22:41 percentage of fault to Dr. Amer if you conclude that he is at fault.

The percentage can be anywhere from zero to 100 percent, and it is for you to decide based on the 09:22:54 evidence.

To show that Dr. Amer's negligence caused or contributed to Ms. Booker's damages, Bard must prove by a preponderance of the evidence that:

One, Dr. Amer had a duty of reasonable care to 09:23:08 Ms. Booker;

Two, Dr. Amer breached that duty;

Three, the breach was a proximate cause of Ms. Booker's injury;

And, four, Ms. Booker suffered damages.

09:23:21 In assessing the conduct of Dr. Amer, the following instructions apply.

A person professing to practice medicine for compensation must bring to the exercise of the profession a reasonable degree of care and skill. This means such degree 09:23:40 of care and skill as, under similar conditions and like surrounding circumstances, is ordinarily employed by the profession generally.

If Dr. Amer, in the treatment and care of Ms. Booker, used that degree of care and skill ordinarily employed by the 09:23:59 profession generally under similar conditions and like

09:24:02 surrounding circumstances, then Dr. Amer was not negligent. If, on the other hand, Dr. Amer failed to use such degree of care and skill, he was negligent.

A doctor is presumed to have performed in an 09:24:20 ordinarily skillful manner. Bard may overcome this presumption by introducing evidence that shows by a preponderance of the evidence that Dr. Amer did not treat Ms. Booker in an ordinarily skillful manner. Expert testimony is required to overcome the presumption.

09:24:40 In order to show that Dr. Amer's alleged negligence was a proximate cause of Ms. Booker's injury, Bard must present expert testimony. An expert's opinion on the issue of whether Dr. Amer's alleged negligence caused Ms. Booker's injury cannot be based on speculation or possibility. It must 09:25:02 be based on reasonable medical probability or reasonable medical certainty.

If you find that the expert's testimony regarding causation is not based on reasonable medical probability or reasonable medical certainty, then Bard has not proved by a 09:25:20 preponderance of the evidence that Ms. Booker's injury was proximately caused by Dr. Amer's alleged negligence.

When determining the total amount of Ms. Booker's damages in this case, if any, you should not reduce the damages because of the negligence, if any, of Dr. Amer. You 09:25:42 should instead determine the full amount of Ms. Booker's

09:25:45 damages, and the Court, in entering judgment, will allocate those damages according to your allocation of fault among all persons or entities whom you find contributed to Ms. Booker's damages.

09:26:00 The verdict form will help you understand the process of assigning fault.

There is no contention by Bard that Ms. Booker is at fault for any of her injuries.

Bard contends that the intervening actions of 09:26:25 Dr. Brandon Kang and certain unnamed radiologists constituted superseding causes of Ms. Booker's injuries.

A superseding cause is a cause of Ms. Booker's injuries that breaks the chain of causation between Bard, on one hand, and one or more of Ms. Booker's injuries, on the 09:26:51 other hand.

If you find that the actions of Dr. Kang or the radiologists were a superseding causes of one or more of Ms. Booker's injuries, then Bard cannot be liable for those injuries.

09:27:06 For Bard to prove that the intervening actions of Dr. Kang or the radiologists were a superseding cause, Bard must show that their actions constituted the sole proximate cause of one or more of Ms. Booker's injuries.

To make this showing, Bard must prove by a 09:27:25 preponderance of the evidence that:

09:27:28 One, the actions of Dr. Kang or the radiologists were not -- let me say that over again. The actions of Dr. Kang or the radiologists were not foreseeable by Bard;

Two, the actions of Dr. Kang or the radiologists were
09:27:45 not triggered by Bard;

And, three, the actions of Dr. Kang or the radiologists were sufficient by themselves to cause the injury.

If Bard could have reasonably anticipated or foreseen
09:28:01 the actions of Dr. Kang or the radiologists, then their actions are not a superseding cause of Ms. Booker's injuries, even if Bard did not anticipate the details or the actions and the injuries they caused.

For the actions of Dr. Kang or the radiologists to be
09:28:20 a superseding cause, Bard need not prove that they were wrongful or negligent.

Bard asserts an "assumption of the risk" defense. If Ms. Booker knew of the G2 IVC filter's defect and was aware of the danger but nevertheless proceeded unreasonably to make use
09:28:48 of the product, taking a risk which in and of itself amounts to a failure to exercise ordinary care for her safety, she cannot later hold Bard responsible for any injury suffered due to taking such a risk.

To establish the defense of assumption of the risk,
09:29:08 Bard must prove by a preponderance of the evidence that:

09:29:10 One, Ms. Booker knew of the danger posed by the G2 IVC filter;

Two, Ms. Booker understood and appreciated the risks of that product;

09:29:23 And, three, Ms. Booker knowingly and voluntarily exposed herself to such a risk.

If you find that Bard has proved each of these elements by a preponderance of the evidence, then Ms. Booker is not entitled to recover for the resulting injury or

09:29:38 damages, and you should return your verdict for Bard.

It is the my duty to instruct you about the measure of damages. By instructing you on damages I do not mean to suggest for you which party -- I do not mean to suggest for which party your verdict should be returned.

09:30:03 If you find for Ms. Booker on any or all of her claims, you must determine her damages. Ms. Booker has the burden of proving damages by a preponderance of the evidence. It is for you to determine what damages, if any, have been proved. Your award must be based on evidence and not on

09:30:22 speculation, guesswork, or conjecture.

Damages are given as pay or compensation for injury done where one party is required to pay damages to another. The law seeks to ensure that the damages awarded are fair to both parties. If you find by a preponderance of the evidence

09:30:48 that Ms. Booker is entitled to recover damages, you should

09:30:52 award to Ms. Booker such sums as you believe are reasonable and just in this case.

Necessary expenses resulting from the injury are a legitimate item of damages. As to medical expenses such as 09:31:10 hospital, doctor, and medicine bills, the amount of the damage would be the reasonable value of such expense as was reasonably necessary.

Ms. Booker seeks to recover not only for her past medical expenses but also for medical expenses that may be 09:31:27 incurred in the future. If you find that the evidence shows with reasonable certainty that Ms. Booker will sustain future medical expenses proximately caused by the actions of Bard, and if you find that the evidence shows with reasonable certainty the amount of such medical expenses, Ms. Booker 09:31:48 would be entitled to recover those amounts, reduced to present cash value.

Pain and suffering are recoverable as damages. The measure of damages for pain and suffering is left to the enlightened conscience of fair and impartial jurors. 09:32:07 Questions of whether, how much, and how long Ms. Booker has suffered or will suffer are for you to decide.

Pain and suffering includes mental suffering, but mental suffering is not recoverable as damages unless there is also physical suffering.

09:32:22 In evaluating Ms. Booker's pain and suffering, you

09:32:27 may consider the following factors, if proven:

Interference with normal living;

Interference with enjoyment of life;

Impairment of bodily health and vigor;

09:32:40 Fear of extent of injury;

Shock of impact;

Actual pain and suffering, past and future;

Mental anguish, past and future;

And the extent to which Ms. Booker must limit

09:32:57 activities.

If you find that Ms. Booker's pain and suffering will continue into the future, you should award such damages for future pain and suffering as you believe Ms. Booker will endure. In making such an award, your standard should be your

09:33:13 enlightened conscience as impartial jurors. You may take into consideration the fact that Ms. Booker is receiving a present cash value award for damages not yet suffered.

Bard must take Ms. Booker in whatever condition it finds her. A negligent actor must bear the risk that its

09:33:36 liability will be increased by reason of the actual physical condition of the person toward whom its act is negligent. Thus, if you find that Ms. Booker's injuries were increased by her existing physical condition, you may award damages for those increased injuries provided you find they were

09:33:58 proximately caused by Bard.

09:34:04 In cases such as this, there may be aggravating circumstances that warrant the award of additional damages called punitive damages. Punitive damages are intended to punish, penalize, or deter wrongful conduct.

09:34:24 Before you may award punitive damages, Ms. Booker must prove that the actions of Bard showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care that would raise the presumption of conscious indifference to consequences.

09:34:47 Ms. Booker must make this proof by clear and convincing evidence. This is a different and higher burden of proof than a preponderance of the evidence, but is less than the standard of beyond a reasonable doubt, which is the proof required in criminal cases.

09:35:04 Clear and convincing evidence is defined as evidence that will cause you to firmly believe, to a high degree of probability, that the requirements for punitive damages have been proved.

If Ms. Booker fails to prove by clear and convincing

09:35:22 evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or entire want of care that would raise the presumption of conscious indifference to consequences, then you may not award punitive damages. Mere negligence, even amounting to gross negligence, will not alone

09:35:46 authorize an award of punitive damages.

09:35:49 In the verdict form, you will be asked to specify whether Ms. Booker is entitled to recover punitive damages, but you will not yet be asked to determine an amount of punitive damages. If you decide that she should be awarded
09:36:05 punitive damages, then you will receive some brief additional instructions, evidence, and argument before setting the amount. There can be no recovery of punitive damages in this case unless there is first a recovery by Ms. Booker of compensatory damages.

09:36:31 Before you begin your deliberations, please elect one member of the jury as your presiding juror. The presiding juror will preside over the deliberations and serve as the spokesperson for the jury in court.

You shall diligently strive to reach agreement with
09:36:49 all of the other jurors if you can do so. Your verdict must be unanimous.

Each of you must decide the case for yourself, but you should do so only after you have considered all of the evidence, discussed it fully with the other jurors, and
09:37:05 listened to their views.

It is important that you attempt to reach a unanimous verdict, but, of course, only if each of you can do so after having made your own conscientious decision. Do not be unwilling to change your opinion if the discussion persuades
09:37:23 that you should. But do not come to a decision simply because

09:37:27 other jurors think it is right, or change an honest belief about the weight and the effect of the evidence simply to reach a verdict.

Because you must base your verdict only on the 09:37:44 evidence received in the case and these instructions, I remind you again that you must not be exposed to any other information about the case or the issues it involves. Except for discussing the case with your fellow jurors during your deliberations, do not communicate with anyone in any way and 09:38:03 do not let anyone else communicate with you in any way about the merits of the case or anything to do with it.

This includes discussing the case in person, in writing, by phone or electronic means, via e-mail, text messaging, or any internet chat room, blog, website, 09:38:24 application -- or application, including but not limited to Facebook, YouTube, Twitter, Instagram, LinkedIn, SnapChat, or any other forms of social media. This applies to communicating with your family members, your employer, the media or press, and the people involved in the trial.

09:38:45 If you are asked or approached in any way about your jury service or anything about this case, you must respond that you have been ordered not to discuss the matter, and to report the contact to the Court.

Do not read, watch, or listen to any news or media 09:39:01 accounts or commentary about the case or anything to do with

09:39:04 it.

Do not do any research, such as consulting dictionaries, searching the internet, or using other reference materials.

09:39:14 And do not make any investigation or in any other way try to learn about the case on your own.

Do not visit or view any place discussed in this case, and do not use internet programs or other devices to search for or view any place discussed during the trial.

09:39:31 Also, do not do any research about the case, the law, or the people involved, including the parties, the witnesses, or the lawyers, until you have been excused as jurors.

If you happen to read or hear anything touching on this case in the media, turn away and report it to me as soon

09:39:49 as possible.

As I've explained before, these rules protect each party's right to have this case decided only on the evidence that has been presented here in court. Witnesses here in court take an oath to tell the truth, and the accuracy of

09:40:07 their testimony is tested through the trial process.

If you do any research or investigation outside the courtroom or gain any information through improper communication, then your verdict may be influenced by inaccurate, incomplete, or misleading information that has not

09:40:25 been tested by the trial process.

09:40:27 Each of the parties is entitled to a fair trial by an impartial jury, and if you decide the case based on information not presented in court, you will have denied the parties a fair trial.

09:40:40 Remember that you have taken an oath to follow the rules and it is very important that you follow these rules.

A juror who violates these restrictions jeopardizes the fairness of these proceedings, and a mistrial could result that would require the entire trial process to start over.

09:40:59 If any of you is exposed to any outside information, please notify me immediately.

The exhibits received in evidence that are capable of being displayed electronically will be provided to you in that form and you will be able to view them in the jury room. A

09:41:22 computer and related equipment will be available to you in the jury room. A court technician will show you how to operate the computer and other equipment, how to locate and view the exhibits on the computer, and how to print the exhibits.

You will also be provided a paper list of all

09:41:43 exhibits received in evidence. You may request a paper copy of any exhibit received in evidence by sending a note through the bailiff.

And we'll swear Traci and Nancy as bailiffs before you retire to deliberate.

09:41:59 If you need any additional equipment or supplies or

09:42:02 if you have questions about how to operate the computer or other equipment, you may send a note to the bailiff, signed by your presiding juror or by one or more members of the jury. Do not refer to or discuss any exhibit you are attempting to
09:42:19 view.

If a technical problem or question requires hands-on maintenance or instructions, a court technician may enter the jury room with the bailiff present for the sole purpose of assuring that the only matter that is discussed is the
09:42:34 technical problem.

When the court technician or any nonjuror is in the jury room, you should not deliberate. No juror may say anything to the court technician or any nonjuror, other than to describe the technical problem and to seek information
09:42:49 about operation of the equipment. Do not discuss any exhibit or any aspect of the case.

The sole purpose of providing the computer in the jury room is to enable you to view the exhibits received in evidence in this case. You may not use the computer for any
09:43:06 other purpose. At my direction, technicians have taken steps to ensure that the computer does not permit access to the internet or any outside website, database, directory, game, or other material. Do not attempt to alter the computer to obtain access to such materials. If you discover that the
09:43:26 computer provides or allows access to such materials, you must

09:43:30 inform me immediately and refrain from viewing the materials.

Do not remove the computer or any electronic data from the jury room, and do not copy any such data.

If it becomes necessary during your deliberations to 09:43:47 communicate with me, you may send a note through the bailiff signed by any one or more of you. And if you do that, please use your number, not your name, for the reasons we've talked about during jury selection.

No member of the jury should ever attempt to 09:44:04 communicate with me except by a signed writing. I will not communicate with any member of the jury on anything concerning the case except in writing or here in open court with the parties present.

If you send out a question, I will consult with the 09:44:19 lawyers before answering it, which may take some time. You may continue your deliberations while waiting for the answer to any question.

Please remember that you are not to tell anyone, including me, how the jury stands, whether in terms of vote 09:44:37 count or otherwise, until after you have received -- I'm sorry, until after you have reached a unanimous verdict or have been discharged. Do not disclose any vote count in any note you send out of the jury room.

A verdict form has been prepared for you. And we've 09:44:58 tried to do it in a way that is self-explanatory. The first

09:45:01 section is titled Liability and it lists the four claims that Ms. Booker is asserting, and it asks whether you find by a preponderance of the evidence that Bard is liable to Ms. Booker on that claim, and you check yes or no on each of
09:45:15 the four claims.

At the end of that section there are some instructions on what you do with the rest of the form based on how you decided those first four claims.

If you found for Ms. Booker on one or more of them,
09:45:29 then you go to the next section which has you establish the amount of compensatory damages, and to the next section which has you address Dr. Amer's fault, and to the next section where you say whether or not you think punitive damages should be awarded.

09:45:44 If you don't rule for Ms. Booker on any of the four claims, it tells you just to go to the end and answer a question.

So we think this will be something that you will be able to follow.

09:45:54 After you have reached unanimous agreement on a verdict, your foreperson should complete this verdict form according to your deliberations, sign and date it, again using the juror's number, and advise the bailiff that you are ready to return to the courtroom.

09:46:13 Counsel, do you have any additions or corrections to

09:46:17 the instructions?

MR. LOPEZ: No, Your Honor.

MR. NORTH: Nothing, Your Honor.

THE COURT: All right. Mr. Lopez, you may proceed
09:46:26 with your closing argument.

MR. LOPEZ: Thank you, Your Honor.

Getting me a stopwatch.

THE COURT: I'm starting it right now.

MR. LOPEZ: Good morning.

09:46:44 First, on behalf of Ms. Booker, who I've had the privilege of representing in this case, and our entire trial team and people who have helped, thank you so much for your service. I know that this is both a sacrifice from your lives, but I hope you understand that it is also a tremendous
09:47:06 opportunity. And when I say that, it's an opportunity to bring people that have never met before, people who are not familiar with something that's been happening maybe in this country for a long time, and have the ability to effectuate change. Change that's good for society, good for all of us.

09:47:35 I'm hoping in the next few minutes I'm going to be able to refocus all of you on what the real issues are in this case. We have these trials, these -- the ability to bring cases like this to court because the Constitution and the laws of Arizona protect our civil liberties, and when they're
09:48:00 violated we get to bring them to court.

09:48:02 And let me tell you what statistics are about. Statistics are what happen when civil liberties are violated.

This case is not about statistics. There are two places we are all equal in this country, the ballot box and
09:48:22 the courtroom. The decision you make in this case may very well be the most important vote you cast in any election. You have the power and opportunity to set testing, marketing, and safety standards wherever you think best. Your verdict will determine the standards not only for the good citizens of
09:48:45 Arizona, but could have resounding effects across this country.

Your verdict will affect the paths that corporations likes Bard should choose when faced with choices between patient safety, people's rights, and their commercial
09:48:59 interests.

You have the power to choose the paths that you, in your collective wisdom as jurors, believe best protects people from getting hurt by dangerous products.

The entire defense case has been about statistics.
09:49:14 Again, statistics only happen when people's rights and liberties are violated. And every time you heard that, and every time you hear it after I sit down and Mr. North stands up to address you, just remember that each one of those statistics is a human being, and one of those is my client,
09:49:31 Sheri Booker.

09:49:36 Ladies and gentlemen, here are the two paths. This is what this case is about, the two paths, the choices that were made in this case by Bard, one of which will be what you want for this community.

09:49:51 Number one, is it -- is it fine with us, as jurors, if companies knowingly sell potentially dangerous products before knowing how dangerous they are once they're put in real live human beings? That is choice one.

Choice two is to say, no, it's not okay if companies 09:50:13 sell a potentially dangerous product until they know it is designed, it is tested, and it is proven to be as safe as possible once we start selling it and exposing people to it.

Or to put it another way, do we make a company like Bard do what we would expect of any manufacturer of any 09:50:36 potentially dangerous product, spend whatever time and money you need to spend to assure safety and effectiveness before you decide to market it or, path number two, do we condone the experimenting and testing of potentially dangerous products in human beings without their consent and the protection each 09:50:58 would get in a monitored and control clinical trial.

I think and I believe in my heart your resounding answer to that last question will be not on my watch.

Now, I want you to recall -- what I'm going to do, and I have a short period of time to do this, I'm going to try 09:51:16 to refocus you to the real issues in this case and some of the

testimony and evidence you may have forgotten about because of the smoke that has filled the courtroom when the defense was putting on this case.

Can we show number 2, Greg.

Recall this testimony from Janet Hudnall's deposition, the marketing directer:

(Video clip as follows:)

"We knew very little about long-term clinical performance of this device when we launched it.

"Um-hmm.

"After a year of commercialization, there are still many questions that need to be answered.

"Um-hmm."

Now, that particular statement -- that was for the Recovery. The statement was they knew very little. When they launched the G2, they knew nothing about what that device was going to do in a human being. Think about that. They did some bench testing, less bench testing than they did for the Recovery, and they put it out in the marketplace and they had no idea what was going to happen.

And then, of course, once they found out what was going to happen, what did they do? They continued to sell it for seven years, even though they knew how to fix it. And they didn't tell anybody.

Now, let's hear what Dr. Altonaga, the medical

director, says about that type of standard.

Number 3, Greg.

(Video clip as follows:)

"Would it be your expectation that when Bard launches a filter for commercial use that Bard would have an awareness about the long-term clinical performance of that device?

"Yes.

"Why? Why would that be important?

"Because I think it's -- it's prudent for the medical device company to understand how its device performs regarding safety and effectiveness."

Okay. I mean, that's the medical director.

The years of repeated and deliberate bad choices by Bard are what this case about. It's not about games this company continues to play, even in this courtroom, in manipulating statistics, making this about statistics. Something we saw them do in this courtroom even in the opening statement. And I expect we'll see it happen again when I sit down.

Now, if you think this case is about statistics, let me show you the one statistic that Bard knows about their product, the G2.

Slide 39, please.

They knew that if they had reduced -- if they had made the changes in design, changes they knew they should have

09:53:46 made to this product, it would have reduced the number of filter complaints by 78 percent. In other words, if you flip that around, when they were selling this product, it had a 450 percent increased risk of causing the type of injuries and 09:54:01 damages that this device caused to Ms. Booker because they didn't make these changes, and they knew that these changes needed to be made. And they knew how to do it. That's what's outrageous. They knew how to do it.

Except for the lawyers in this case, and now you all, 09:54:23 the FDA doctors, their own sales force, hospitals, patients like Sheri Booker, they never came clean with what was really going on behind the scenes with the information that they had.

Remember Mr. Carr: That's proprietary, we don't share that with anybody.

09:54:42 And when they knew they were selling an unreasonably dangerous device, they knew they needed to stop selling it until they fixed it. And they didn't do it.

Once again, you begin -- once you begin to discuss this case in your deliberations, you will all see quite 09:54:58 clearly that this case is about Bard knowingly and deliberately choosing the wrong paths and the wrong choices, and those choices always best suited their needs, their wants, their commercial interests, and never the path that would have spared good, decent people like Sheri Booker from being 09:55:19 exposed to the product that they knew was dangerous, that they

09:55:22 knew needed to be fixed, that they knew how to fix and didn't do it. Instead, they find ways to expand their market share.

Their focus remained at all times on what is best for their competitive advantage and bottom line. They don't have
09:55:38 the right to sell a product like that and say buyer beware.

This thing was implanted in maybe the most vulnerable location in the human body, the direct pathway to the heart. I mean, if there was ever a product where strength and stability was the most important feature that you shouldn't
09:56:02 compromise, it should be something that, if it goes wrong, it goes into the organ that keeps us all alive, our hearts. And they knew that. They knew that pieces were going into people's hearts. They knew they had a Recovery filter that 19 times did that. And that they want a pass because when they
09:56:24 redesigned it, they fixed that part and created a whole new cascade of problems that they told no one about.

Simple rules I think we can all understand.

If a company does not know how a product is going to perform in human beings, they should not sell it. Period.
09:56:53 They did not know. They knew how it would work in sausage casing and PVC pipe. Kind of. Because, remember, they did some tests and they went, oh, we failed that test so it must be the sausage we bought this time.

And if they know how to fix it -- and this is -- if
09:57:13 we didn't have laws, and you heard this, you would think they

09:57:18 have a moral and ethical obligation to fix it before they sell it.

Ask yourselves, who would have been harmed had they chosen that path, fixing it? Taking it off the market, not
09:57:36 exposing people. Not making people be their subjects to see how it works without telling them that's what they were doing. Bard. Their marketability. Their ability to stay on the market and compete in this marketplace that they knew was a big one.

09:57:56 But who would have been spared? Sheri Booker. And apparently 78 percent of the other people they put -- they allowed this device to be implanted in.

The bottom line is they involved my client -- I'm just going to say it like it is because these are the facts --
09:58:14 in a large-scale experience -- experiment without her consent.

Ladies and gentlemen, they didn't have that right. They don't have that right. They can't just decide that based on statistics she's within some kind of acceptable range based on an article that was written about devices that were sold 20
09:58:37 years before this one. They don't have that right.

They violated Sheri Booker's civil liberty. They didn't have the decency to tell her doctors to pay close attention to this device based on what they knew.

So let's assume they didn't want to tell anybody
09:58:56 about the inner secrets about how this device was really

09:58:59 performing. Don't you think that the least they could have done is gone to her doctors and said, you know, pay close attention to this because we've got -- it may tilt a little, it may start to move down. Once that happens you probably
09:59:13 ought to take it out. I know it's a permanent device that you may want to leave in, but under those circumstances take it out. Because they knew that if they kept it in, if that thing stayed in longer, like it did in Ms. Booker, that they would not be able to get it out, that it would break, it would
09:59:29 shatter, and it would do exactly what happened in her body.

Now, I could go through their excuses, but it would take me way too long to do that. I've already mentioned, well, this is not as dangerous as the one we replaced, what's the beef? We fixed one bad thing about the Recovery, you
09:59:52 should be patting us on the back for that.

And let's just forget about the fact this device is doing something we've never seen before in any device. It has this constellation, this cascade of problems that was revealed to them in the EVEREST study. And, of course, their go-to
10:00:10 excuse is, oh, these are known complications.

I mean, imagine that excuse if we allowed auto makers to have that excuse. You know, a known complication is, you know, people drive crazy, there's drunk drivers, people get in accidents. And then you say, well, you didn't put seat belts
10:00:29 in your car. You didn't put airbags in your car. You didn't

10:00:32 protect the gas tank.

Well, the auto maker comes in and goes, those are known complications. People know when they get in a car that you can get in an accident.

10:00:41 No, they're not forgiven for doing that. Known complications.

The government agency who regulates this industry, which doesn't test, design, profit, or have any experience in the research and development or marketing of these devices, 10:00:56 never told them to stop. That's their excuse. They need to be -- so their excuse is to continue to sell a dangerous product, that they know is dangerous, they know how to fix it, they don't tell the people they're giving it to that there's -- they're involved in this experiment to give them 10:01:13 more data to build their next best device, and their excuse is, the people that we didn't give information to didn't tell us to stop.

Well, we saw what happened at FDA, when FDA woke up about ten years later and found out they were indeed hiding 10:01:35 important safety information from them. I don't have time to talk about that, but I'm talking about the warning letter that came into evidence.

Are we to believe that they were more forthcoming and transparent with FDA than they were with their own sales 10:01:53 force? With their own consultants? With their customers?

10:01:56 And even the experts that testified in this case? They didn't share that information with them. But they want you to believe, boy, we were transparent and gave everything to the FDA.

10:02:06 The experts that they collectively have paid over a million dollars to help defend them in this case, and Mr. North had the audacity to say we were going to defend this case -- we were going to prosecute our case with high-priced experts.

10:02:22 Maybe the excuse is something went wrong with the sausage casing. Remember Mr. Tessmer said, well, I'm not sure about the devices, they may not have been good devices.

I mean, did somebody sit on them before the test? Did -- that was just an excuse because they failed the test. 10:02:38 And they knew as soon as they fail a test like that, that the law requires them to stop selling it.

Did they share those bad tests with the FDA? You bet not.

Let me summarize some of the evidence. I know I'm 10:02:58 going to be cut short here because there's a lot of it, and I'll try to synthesize it down. Again, I'm just -- I want to refocus you to the real issue in this case. Mrs. Booker -- Ms. Booker got an experimental device that was still being tested. This company knew was defective. This company knew 10:03:16 that the adverse events were piling up. It was something

never before seen in IVC filters, and they didn't tell her or her doctor. That is outrageous. We cannot allow that to happen. We cannot -- that's the path that we need to tell corporations, no, no, don't go down that path. That's the path that starts with all those light bulbs -- those lighted eyeballs in the tree. We don't know what's in those trees. Don't go down that path.

Recall Dr. Asch. This is how Bard started this journey. Dr. Asch, they hired Dr. Asch. Dr. Asch, I mean, I didn't even have to ask him this question at the end, but then I asked him I said, by the way, did your study in any way establish long-term permanent safety and effectiveness? I mean, it was like why do you have to ask that question? It was so obvious. Of course the answer was no.

But here it is, the submission, the 510(k) submission that Bard made to FDA that started their path on trying to grab market share in a booming new industry called retrievable filters. They told FDA this, and they signed it in a truth and accuracy statement and said no material fact was omitted.

However, Dr. Asch's data relative to complications during filter placement, recurrent pulmonary embolism, death, filter migration, et cetera, provide clinical data to support a determination of substantial equivalence as a permanent device.

I mean, I don't know that it gets any more false and

misleading than that.

That's their first communication with FDA. But now we're supposed to believe they were transparent with FDA.

So they put the device on the market anyway. They know the one and only time it gets challenged by a clot that would have had any clinical significance, it starts to move the device towards the heart. One time. The first time. 100 percent failure in a clinical trial. A pilot study.

And they tell Dr. Asch, well, we're going to do a long-term clinical study in Europe. Well, I don't care whether it's in Europe, Australia, Canada, or here in Arizona. They needed to find out what was wrong with that device and they never did. They just put it out blindly into the world without knowing what was going to happen. And guess what happened? 19 people died from that Recovery device. And the only reason why they kept it on the market is because they needed it for their next 510(k) application, the G2, because they didn't want to have to go through the more stringent, more expensive, more lengthy process of doing a PMA, which they would have had to do a clinical trial.

We saw that -- remember the slide of Mr. Randall? They wanted to go from a G2 to the next device, quote, without having to do a clinical trial.

Slide 4, please.

Can I have slide 4, please.

10:06:33 Okay. Here's the truth in accuracy. This is what they signed. This is how they got clearance. Note that the data and information submitted is truthful and accurate. No facts material for review of the substantial equivalence of 10:06:47 this device have been knowingly omitted from this submission.

More like a little tidbit like Dr. Asch said, don't sell this thing until you do a clinical trial because I'm concerned about the fracture and the migration that happened in my trial.

10:07:00 And a little tidbit like the ethics board in Canada said to stop the study after one fracture and after one migration.

Then they put it on the market and what happens?

Can I have slide 14, please.

10:07:16 (Video clip as follows:)

"Users can be swayed by ease of use, low profile and aggressive marketing even in the absence of solid clinical history and in spite of documented negative clinical experiences.

10:07:32 "Yes."

That's where their attention turned. Not to doing a clinical trial, but knowing that doctors can be swayed with their 100-plus sales force, with aggressive marketing. And in spite of negative clinical experience.

10:07:49 That's what the evidence in this case showed.

10:07:54 Then they go into full market launch. And remember the testimony of Natalie Wong, a nice lady. I thought she was a very sweet young lady. And who was asked to do a test in May of 2004 where she was supposed to do a statistically -- a
10:08:09 statistical analysis. They want to start to talk about statistics, we have to talk about that one where Natalie Wong did a statistical analysis to see, do we have something going wrong really bad with our Recovery filter?

And guess what? She did that study, she did those
10:08:28 statistics, and she found that with 95 percent certainty, substantially equivalent, the Recovery filter was causing more deaths than any other device on the market, including their Simon Nitinol filter.

Isn't that -- I mean, that is not a stop sign. I
10:08:45 mean, that is a giant wall to stop.

Our device is causing more fatalities than the device that allowed us to get it on the market. But also against our competitors.

So what did they do?

10:09:01 Slide 8, please.

Do they go to ASU and go to the engineering department? Do they go to the medical center here and find doctors who might be able to help them figure out what they should do or not do and maybe how to redesign this thing and
10:09:16 whether or not, you know, these things are too dangerous? No.

10:09:20 What they do is they go to a PR firm. And they decide to hire Dr. Lehmann. And they come up with this little quip in case the media -- and they expected the media was going to start coming at them. Bottom line: Good filter, severe case, bad 10:09:39 out come, deep regret.

So sad, too bad, became their mantra.

And this is a simple story we should repeat again and again. Not Natalie Wong's statistical analysis. Not the fact that they knew this was going to happen from Dr. Asch's 10:09:56 clinical trial. No, let's just find a good story to tell and maybe deflect people away from what's really going on with our device.

And you'll see this, this is Trial Exhibit 546, where they try to figure out how do we deal with migration? I don't 10:10:13 have time to go into it, but I urge you to look at Trial Exhibit 546.

Slide 9, please.

Then they have -- I mean, the mere fact they're having a health hazard evaluation should tell you that 10:10:25 something serious is going on. Just the mere title of that. You almost don't have to read it.

This is in July of 2004, after six months of full market launch. They've had 20 arm fragments in 14 cases, three patients had detached hooks and arms. 11 of the 20 10:10:42 arms, 55 percent, remain in the patient. Like Ms. Booker.

10:10:47 And six patients, the arms migrated to the hearts or lungs. Known complication. That's their excuse. Keep selling it. Known complication. We can probably find some statistical way of justifying that.

10:11:03 Let's go to the next slide, Greg.

Then Dr. Ciavarella says there is no way predict which patients will develop this complication. Here's what he recommends: More frequent monitoring of the filter once placed may facilitate discovery of abnormal placement or

10:11:21 indeed of a fractured filter.

Had they only followed that advice with Ms. Booker and her doctor.

Had they only listened to Dr. Ciavarella.

Fast-forward to December 2004. They didn't even tell

10:11:43 Dr. Cohen, one of their consultants, who had a death at Temple. And guess what, Doctor, five patients before yours died of the same consequence.

Don't you think they should have told Dr. Cohen so he wouldn't have had statistic number six? Because I'm sure if

10:12:00 they would have told Dr. Cohen, somebody they were paying that was a consultant to them, they didn't have the decency to tell him, then they just allowed two of his patients to die.

This is in December --

Skip this, Greg. Go to the next one.

10:12:21 So they let another six months go by after that last

10:12:25 health hazard evaluation, and they hire a consultant. And the consultant determines, after looking at all of the data that was available -- remember yesterday I heard Mr. North and Mr. Modra say, that was the best data we had; right? This
10:12:38 adverse event data.

Well, here's what the consultant found out: That reports of death, filter migration, movement -- meaning movement, IVC perforation and filter fracture associated with Recovery filter were seen in the MAUDE database at reporting
10:12:54 rates that were 4.6, 4.4, 4.1, and 5.3, higher respectively than the reporting rates of all other filters. And these differences were statistically significant.

What you don't know is compared to the Simon Nitinol filter, they couldn't do a calculation because it was zero for
10:13:14 Simon Nitinol filter for migration deaths in the entire history of that device, and by the time this was done they had ten.

Can I have 15, please.

So before they know how this device is going to
10:13:34 perform in a single human being, they go -- they develop this marketing brochure. And like Mr. Carr said, you heard all the history how things change, this is the message they had out in the open medical community for six or seven years, that the G2 filter combines the best design features of Bard's existing
10:13:54 vena cava filters to create a brand-new permanent filter

platform taking strength and stability to a new level.

Like my colleague Ms. Zaic said in her opening statement, what they didn't say is to a whole new level. That that's the part they left out.

After the experience with Recovery filter and realizing that we probably should find out what's going on with these devices, they didn't have the decency to take the time and effort and spend the money to do a clinical trial on a G2 to see whether or not those designs that they thought they fixed, that looked pretty good in sausage casing and tubing and maybe in sheep, wasn't really going to work in human beings.

Here's what happened with the G2.

Slide 17.

It's been on the market two or three months. And their medical director, someone they continue to ignore who said, we should be monitoring these patients, they ignored him again.

I don't have to read this to you, you remember this one. He's looking at the complaints, he's seeing how this is performing in a clinical world among clinical subjects who have no idea they're part of an experiment. Why are we using the G2, for crying out loud? We have the SNF device that has had no deaths. This had two fractures in the last ten years. Why are we using the G2?

10:15:28 Slide 31.

And they knew how to fix it.

They knew that there was another device where they had caudal migration and they redesigned it. This is April of 10:15:40 2006. Alls they had to do was flip the two hooks. But you know what they knew? If they did that, they would have had to go back to FDA to do a new 510(k) clearance.

And remember, they were launching the EVEREST study because they wanted retrievability. I mean, they launched the 10:15:57 EVEREST study after they already knew that this device was too dangerous to sell to anybody.

And why did they launch the EVEREST study? Because they wanted to expand the marketplace and get retrievability. They admit that was not a long-term safety study. That study 10:16:14 was about retrievability.

Well, guess what the EVEREST study revealed to them?

Can I have -- let me have slides 34 through 39.

I promise you I'm not going to take you through these slides again, except for this first one.

10:16:29 They know that there's -- they knew from the EVEREST study -- they knew this before the EVEREST study, that caudal migrations were associated with tilts, 43 percent of the fractures were associated with tilts.

And, Greg, just -- if you'd go to the next one.

10:16:43 I want to show you --

10:16:45 Go to the next one.

Go to the next one.

And go to the next one.

Okay. Now take that down.

10:16:54 I want to show you those because this constellation, this new problem, this new serious consequence never seen before, they did those circles because they knew that this device for some reason wasn't about a fracture alone. A perforation, a tilt, or a migration, that all those things 10:17:13 worked together to wreak havoc in people's bodies. That's what those circles were about.

THE COURT: Mr. Lopez, you're at 30 minutes.

MR. LOPEZ: Thank you, Your Honor.

Slide 19.

10:17:28 I'm not going to -- this just came into evidence yesterday. I wanted to put it up because I fought like the dickens to get this and it came into evidence. I think Mr. O'Connor is going to talk about it. This will show what they knew in January 2006 and what their CEO and COO knew and 10:17:44 what the president of the company knew about the performance of the device. I urge you to look at Exhibit 4327.

And we know about Natalie Wong's unacceptable risk. Again, not a stop sign, that's a road block. And did they stop? Did they stop to do it, even go to Canada to do a 10:18:05 study? And what do you think the Canadian Ethics Board would

10:18:09 have done had they known about the way the G2 was performing?

And then Dr. Kandarpa --

Slides 32 through 33, please.

And Dr. Kandarpa, he's the medical director -- I

10:18:26 mean, the medical monitor of this EVEREST, and 100 patients enrolled. And here's what's revealed in those --

Go back to the last one, Greg, a little bit.

-- 84 adverse events in 100 patients. 49 serious adverse events in 100 patients.

10:18:44 And here is what Dr. Kandarpa said in his report. He expressed concern about the number of reported tilts hitting approximately 20 percent, and thought that Bard may want to closely evaluate this. He was telling them this design is not -- you have to look at this device.

10:19:05 And Dr. Kandarpa wanted to know if we were concerned that almost 50 percent of the patients have reported AE and SAE.

Well, they weren't concerned enough to not stop the study, get their retrievability indication.

10:19:25 And recall the testimony from Mr. Van Vleet. Mr. Van Vleet -- Dr. Lehmann, you heard his name earlier, was a consultant, and they wanted Dr. Lehmann to agree to change the migration definition so that it would reduce the number of migrations they would have had to report to FDA and to the

10:19:46 rest of the world. Dr. Lehmann said no.

10:19:49 Dr. Lehmann said, you can't put in your submission that the EVEREST trial establishes substantial equivalence for safety to anything and -- about anything because the evidence does not show that, and they did that anyway. Because -- and 10:20:07 what did they do? They fired Dr. Lehmann. They didn't want him to get in the way of that submission.

I'm going to show you slide 39 again because I want you to -- if you decide that this case is about statistics, you just remember that this company had not only the 10:20:30 opportunity, they had the absolute duty to take steps to reduce, if they were going to keep it on the market, which they shouldn't have even launched it, by 78 percent, by their own admission, and they didn't do it.

Let me talk to you now about my client, the privilege 10:20:49 and the honor I've had to represent her. And, you know, I -- if you didn't know much about Sheri Booker, I think you found out just about all you needed to know about her when her son Shomari testified. I mean, if that doesn't say who Sheri Booker is, I don't know what does. The love, I mean, 10:21:09 just the quality of that young man. Just the quality of what he said and his life and his experiences and what he's accomplished in such a short period of time.

We know that Sheri is 48 years old now. I believe she was 37 when she got this device. Mother of two children. 10:21:32 Battled cancer, beat that.

10:21:39 And she trusted that when she got a medical device, just like we all would, that that device was well tested, proven safe and effective in a clinical trial, and that every single thing that a company knew about that device would have been shared with her doctor so that her doctor would share it with her. And that didn't happen. And they had two years to do that. They kept this brochure bragging about their strength and stability. They had two years.

And you know what they want to do now? They want to say that Dr. D'Ayala didn't read the IFU. Well, who cares. There is nothing in that IFU that would have conveyed to Dr. D'Ayala what the true risks and problems were with this device.

I'm sure Sheri didn't know that when this two or three months into the marketing of the G2 about a year and a half before she got it, that this company said that we've got problems in and defects in our design and we better redesign it and put hooks going the other way, and that the company took no steps to do that. I bet she didn't know that.

10:22:46 Then they -- you heard Your Honor's instructions, they want to blame the doctors.

They want to blame Dr. Amer, who is, by the way, a diagnostic radiologist, who was looking at an X-ray to see whether or not Sheri had some problems with her back. A diagnostic radiologist who they don't even call on because

10:23:10 they don't put in these devices.

A diagnostic radiologist who would have been nice because he would have been someone who have would have come along in the chain of events with any patient, would have been 10:23:25 nice had they told diagnostic radiologists, by the way, our device is fracturing, it's tilting, it's embedding itself in the side of the wall, and like Dr. Ciavarella said, it is tipping like a Christmas tree and poking through people's arteries -- the vein into the aorta. Had Dr. Amer only known 10:23:45 all that before he looked at that X-ray.

Might they have helped him a little to look at that part of her body because, oh my gosh, this is a G2, this may be a G2 Bard filter, I better pay close attentions to this? No, they didn't do that. But they want to now come in here 10:24:05 and say Dr. Amer, bad, bad, bad. You didn't look at our device to see that it was starting to break up in Sheri Booker's body.

You heard the testimony of Sheri's doctors and, again, you heard about --

10:24:26 Can we have the slides on Sheri Booker's injuries, please.

Well, guess what? All those things that were predicted in the early weeks that this device was on the market and all of the things that were predicted with all 10:24:43 those intersecting circles from the EVEREST trial, they

10:24:47 happened to Sheri Booker. In fact, it is probably -- it might be -- I mean, it was probably the worst case of anyone in the EVEREST because, you know what, those people were only in the trial for six months. We only -- who knows what would have
10:25:01 happened to those 39 people that went out and they didn't follow. I mean, I would hope they would have followed them, but I'm sure they didn't.

They knew this was going to happen to her. A filter tilt. 6 perforations. One 8-millimeter penetration into her
10:25:18 aorta. Three fractures, one to her heart. Surgery in July of 2014.

Now, Bard sets in motion this cascade of medical intervention, and they want to blame the doctors because they don't quite do it exactly the way they think they should have
10:25:34 done it. How dare they. I mean, that's outrageous. These doctors are stuck having to deal with a product they knew this was going to happen in a patient, and they want to blame the doctors because doctors now are faced with having to do things that maybe they don't -- they never had to do before, go in
10:25:56 and try to take this thing out of Sheri Booker's heart without having to open up her chest to do open heart surgery.

You know, bad doctor. Why did you do that?

She now has deterioration of her tricuspid valve, potentially requiring valve repair surgery. 60 percent
10:26:18 mortality or survival rate, ten years. This is what this

device did to her.

Now, here may be the worst thing right now in her life: She has a filter fragment in this largest vein in her body, and you're going to see, by the way, in one of the -- a piece of that document we just got in, that one of these things dislodged, a report was it dislodged from where it was in the vena cava. They know this could happen. It went into a patient's heart. So she has to think about this for the rest of her life. She's at risk of this fragment migrating to her heart and going through this process all over again. No wonder she's wants to make sure she's 15 or 20 minutes from a hospital wherever she goes. She needs lifetime medical care.

Her past medical bills, you saw, they were $267,627.99, and the present value of her future care, $242,023, for a total of $509,650. You have that in evidence.

Now, here's where -- you know, this is where I feel almost inadequate, because now I've got to talk about what is this fear, this anxiety that she now lives with and has to carry with her for the rest of her life? What must it have been for her to have gone through what she went through when she found out that this piece was in her heart and they had to get it out or it was going to kill her?

I don't know how to -- I'm sure if this was about the proprietary information that Bard keeps from doctors that they talked about, you know, they'd be able to get someone forensic

10:28:06 and say this is worth $20 million if this gets out, because if people know that our tests failed it would show that our market share would dip and we'd loose $20 million over the next ten years.

10:28:19 I mean, we can't do that with human life. And what's stripped from us as human beings when something like this happens. I mean, you know, don't I wish this was Steph Curry, and I could say, well, you know, they ended his career. I'd be able to show you his contract. But I'm going to do the

10:28:38 best I can. That's all I'm going to tell you. And you are the conscience of the community, you feel what you need to feel about this part of the case.

24 hours a day, every minute for the next 34 years, Sheri has to be concerned about whether or not she's going to

10:28:57 need this open heart surgery or whether or not this piece is going to migrate to her heart. I mean, it's like every moment she worries about that. I bet when she's sleeping she's probably thinking about that.

So I thought about it in terms of, you know, time.

10:29:17 At first I thought, you know, a dollar a minute. I mean, what -- how do you -- what's -- what do you pay for having to live through something like this? What is it? What value do you put on that? What's been stripped from you in dollar figures? I don't know.

10:29:31 But I think I have to suggest something to you. I

10:29:37 think 50 cents a minute, every day, 24 hours a day for the next 34 years of her life is the least. I mean, that's a fraction of what they paid their experts to come in here and defend them. Not what they paid them to do research and find 10:29:58 out what root cause analysis can fix these problems, but what they paid their experts to come in here and play their statistics game.

I'm just asking that Sheri be paid $30 an hour to deal with this. Now, when you add that up, it adds up to a 10:30:17 large number. But believe me, it is -- because she's going to live 34 more years with this. You may think this number is too low. And the best I can do is suggest to you that in relative terms, I think it's way too low. But I'm going to tell what you that number is. It's $8,935,200. You can do 10:30:42 the calculation yourself.

And for her past that she went through, I'm going to let you deal with that. I'm going to let you go in the jury room and say what -- let's look at that in real life human terms and decide what Bard should compensate her for for 10:31:01 having gone through that pain and suffering and misery because they allowed this dangerous product to be put on the market.

Time, please?

THE COURT: 45 minutes. Well, 30 seconds short of 45 minutes.

10:31:14 MR. LOPEZ: Thank you, Your Honor.

10:31:15 You are a good timekeeper.

Can we go to the jury instructions.

Now, I don't have -- you're going to get these instructions.

10:31:29 I'll come back to that, Greg.

Okay. The burden of proof, I think, is very important in this case because I think Mr. North wanted you to think this was a criminal case when he first stood up because he talked about his client being wrongfully accused.

10:31:51 Well, this is a civil case. And the burden of proof is a preponderance of the evidence. And it means that our evidence just has to be probably more true than their evidence. It's like the scales of justice. If what we showed you is evidence tips the scales in favor of the elements in

10:32:11 this case for the plaintiff, then we win.

In other words, you can still have doubts about certain things. And you might. When you see the statistical show that is going to happen, you might say, well, maybe there's some doubt. If you do, if, on balance, the evidence

10:32:29 weighs more heavily in favor of the plaintiff, you find for the plaintiff.

Strict liability design defect. I mean, they admit this. I almost don't have to walk you through some of these slides because they admit that their device was defectively

10:32:45 designed.

They admit -- I mean, as soon as it's called an unacceptable risk by Ms. Wong in her analysis and she does their internal DFMEA, they've already told you that the risks outweigh the benefits and that they ought to redesign it. But you'll see testimony after testimony, document after document where they acknowledge we have design issues. We have to redesign this product to fix it.

And we know it was because of their failure to redesign it that it caused injury to Ms. Booker.

Then we have strict liability design defect.

The next slide.

And the design of the product outweighs its utility of that particular design. Well, we know that. I mean, you can't introduce a whole new constellation of risks that could potentially kill you or cause serious injury in exchange for something that we don't even know whether it works.

By the way, we're not taking on the whole IVC industry. I don't know whether these things work or don't. Because no one's ever done a clinical trial.

The only thing that Dr. Streiff was saying and Dr. Rogers was that all of the data seems to suggest that maybe they don't.

And then under those circumstances, ladies and gentlemen, if -- you're going to make something that maybe doesn't even work, that maybe your standard of taking out the

risk should be the highest it possibly could be because we don't know if it works. We know the Recovery filter didn't work when it was challenged, but don't say, well, we get to be in this range because we get to look back at what happened with older devices that were between 1 and 2 percent fracture rate, therefore we're okay, even though we know we have a bad design.

You know, if you don't know for sure it's going to work, please don't introduce into our bodies new risks, new complications. Maybe new -- maybe problems that are worse than the one that you're trying to protect against. Please don't do that.

Strict liability design defect. Again, you'll have these instructions. I think these are fairly straightforward. I don't think there is any evidence to suggest that these devices did not -- were not strictly liable, that this company is not strictly liable for their design defects. They could have avoided the danger, and we saw that in even some of the evidence I just showed you.

And then the failure to warn --

If we can go to the failure to warn slides.

I mean, this is -- this is a no-brainer. I mean, they have an IFU that has all these known complications in it, but do they -- if you look at the internal -- what was behind the scenes, the internal data, the internal information, what

they were discussing internally about this product, I don't think there's anyone in the world who doesn't think that the company should have shared that with them. And they didn't share even an ounce of that with Ms. Booker or her doctors. I mean, this -- frankly this shouldn't even be a warnings case because this device should have never been an option for her based on the evidence that you've seen.

Which takes me to the punitive damage instruction.

This is clear. There is clear and convincing evidence that Bard showed willful misconduct, malice, fraud, wantonness, oppression -- and here's the phrase you need to focus on -- that raises the presumption of conscious indifference to consequences.

I mean, how can that not be true about their conduct, conscious indifference to consequences, when they put out a device on the market that they have no idea is safe and effective. That they allow a device to stay on the market when they know it is dangerous. When they allow a device to stay on the market when they know how to fix it, yet they don't do it.

I -- I can't explain to you why that is, other than to say that what I said earlier, they have to take that down and they have to do a new 510(k) just to flip the hooks to save the Sheri Bookers and 78 percent of the other people that they're selling this to. They don't get the retrievability

10:37:26 for a long time.

And they know -- you saw the graph, retrievability product, permanent products. They didn't like that flatline for the Simon Nitinol filter. They liked that peaked line of
10:37:40 retrievability.

And the Simon Nitinol -- I mean, the G2 filter was permanent at the time. They need it for their good, for their benefit, for their needs to get retrievability. And they left that product on the market and they didn't tell anybody. They
10:37:56 continued to sell it with that same brochure about taking strength and stability to a new level.

Ladies and gentlemen, again, I hope that I accomplished at least one thing, and that is to refocus you on what I believe is the case, is why we're here. It's not about
10:38:23 statistics. It's about civil liberties, it's about patients and people's rights, about not taking those rights away from them. About allowing them to make their choices based on what they know. Not to make those choices for them.

The companies do not have the right to make choices
10:38:45 for any of us. Give me the information, please. Let me look at it. Let me decide whether or not I want to take the risk of having this device in my body or getting in that car or buying that toaster. Or buying that automobile or that bicycle or that kid's toy. I want to know everything that's
10:39:08 good about it, I want to know everything that's wrong about it

10:39:11 so I can make that decision. They did not allow Sheri Booker to make that decision.

There's no way they can stand up here after I sit down and say, yeah, we told Sheri Booker and her doctor 10:39:23 everything she needed to know about what was going on behind the four walls of our company before she got that device.

Thank you.

THE COURT: All right. Thank you, Mr. Lopez.

Ladies and gentlemen, we'll take the morning break 10:39:38 from now until five minutes -- no, ten minutes to the hour. No. Five minutes to the hour.

Please remember not to discuss the case yet.

And we'll come back and hear the defense closing.

We'll excuse the jury at this time.

10:40:08 (The jury exited the courtroom at 10:40.)

THE COURT: All right. Plaintiff's Counsel, you used 53 minutes.

We'll be back at five minutes to the hour.

MR. STOLLER: Sorry, Your Honor. What time?

10:40:22 THE COURT: Five to the hour.

(Recess was taken from 10:40 to 10:51. Proceedings resumed in open court outside the presence of the jury.)

THE COURT: Thank you. Please be seated.

Counsel, I wanted to come in before the jury to ask 10:53:29 you, Mr. O'Connor, if you want me to give you like a

10:53:31 five-minute warning or just --

MR. O'CONNOR: That would be great. I appreciate it. Yes.

THE COURT: Okay. I'll do that when there's five

10:53:41 minutes left. Okay.

MR. STOLLER: Did you want to discuss the verdict form before we bring the jury back?

THE COURT: No.

(The jury entered the courtroom at 10:54.)

10:55:58 THE COURT: Please be seated.

Mr. North, you may proceed.

MR. NORTH: Thank you, Your Honor.

May it please the Court, ladies and gentlemen of the jury.

10:56:11 Like Mr. Lopez, I would like to start off by saying thank you. Thank you for myself and my team. Thank you for the -- on behalf of the men and women at Bard. We all know, as the plaintiff's team does, what a sacrifice and what an imposition it is for each of you to spend three weeks of your

10:56:30 lives to resolve this dispute between Ms. Booker and Bard. And we appreciate very much, all of us, your dedication and your patience. And I know you all have shown a lot of patience during the course of this three weeks.

Before I talk about the issues in this case, I want

10:56:49 to talk briefly what is not at issue, because I think that's

10:56:54 important.

What is not at issue in this case is Ms. Booker. Judge Campbell instructed you, and it will be in the instructions you take back to the jury room, that Bard is not 10:57:07 claiming that Ms. Booker did anything wrong. We are not disputing the fact, nor could we, that all of us, as human beings, have sympathy for what has happened to Ms. Booker. What has happened to Ms. Booker was certainly not her fault. But that's not an issue in this case.

10:57:30 The Judge has instructed you and we believe the evidence shows that.

What is at issue in this case?

In looking at the issue, I ask you to remember what I said at the beginning of the case, in opening statement: To 10:57:47 wait and listen to the whole story. Not to listen only to the few documents that the plaintiffs put on or the snippets of depositions taken years ago, but to wait and hear all of the witnesses and all of the story. Because if we believe the snippets and the part of the story that Mr. Lopez presented in 10:58:10 opening statement, during the course of his case, and particularly here today in his arguments, we would never be here. But we believe there is a lot more evidence that you have seen, and the whole story tells a very different picture from what Mr. Lopez suggested.

10:58:31 But let's talk also about, before we get to the true

10:58:33 issues in this case, whether the G2 is defective, whether its warnings were adequate, and whether they were the cause of Ms. Booker's injuries. Let's talk about a few more things that aren't at issue.

10:58:46 We've all heard the term "red herrings." Something that distracts attention from the real issue.

And, ladies and gentlemen, I submit to you there are three red herrings in this case that have taken up more of our collective time than they ever should have.

10:59:06 The first one is the Recovery filter. This case is not about the Recovery filter, ladies and gentlemen. The Recovery filter was not implanted in Ms. Booker.

But yet much of the evidence you have heard during this entire case has dealt with the Recovery filter.

10:59:29 Apparently trying to make us all forget that, as Mr. Chanduszko explained as the first witness in trial, he helped design the G2 to make it different than the Recovery filter, to make it more migration resistant. To make it more fracture resistant.

10:59:52 That is the filter that was implanted in Ms. Booker, as we all know, not the Recovery filter. Yet much of the plaintiff's evidence that we have heard during this trial did not concern the G2 filter, but concerned only the Recovery filter.

11:00:12 Evidence such as Dr. Asch. He conducted the initial

11:00:17 clinical study regarding the Recovery filter in, like, the 2001 time frame, and then he had no further involvement. The G2 was not introduced to the market until 2005, and he never had any involvement with the filter that was implanted in
11:00:36 Sheri Booker.

Mr. Lopez had Alex Tessmer, an engineer from Bard, on the stand for two hours in the second and third days of the case, I think it was March 15th and 16th. He testified for over two hours to Mr. Lopez's questions about two tests he
11:00:58 performed regarding the Recovery filter. He did not participate in any tests concerning the G2 filter that was implanted in Ms. Booker.

Again, ladies and gentlemen, I submit to you, a red herring.

11:01:15 We just saw more than half of Mr. Lopez's closing argument dealt with deposition clips, such as Janet Hudnall, regarding the marketing and development of the Recovery filter.

Clips of other witnesses, such as Jason Greer, who we
11:01:34 saw on March 22nd. Again, dealing with Recovery filter complications.

Ladies and gentlemen, I submit to you that all of this evidence about the Recovery filter is a red herring. It's meant to distract you. It's meant to make you inflamed
11:01:54 because there were reports, unfortunately, of 19 people who

had a Recovery filter migrate to the heart.

But that's not what this case is about. The filter, the G2 filter, did not migrate as a whole filter to Ms. Booker's heart. In fact, every witness, including their experts, asked in this case admitted that the design changes Bard made regarding migration to the Recovery filter worked. There is not a single report of the G2 filter ever migrating to a person's heart and causing death. Out of over 130,000 sold.

Ladies and gentlemen, the G2 filter was implanted in Ms. Booker, and all of this evidence about the Recovery filter, I submit to you, is a red herring.

Another red herring in this case is the Simon Nitinol filter. First developed in 1990, only available as a permanent filter, could not ever be retrieved without a massive open surgical procedure. Yet the plaintiffs kept trying to argue, well, that's a viable alternative here.

Maybe Simon Nitinol filter should have been implanted in Ms. Booker. That is a design alternative.

But let's look at what the testimony in this case said about the Simon Nitinol filter. And why it is a red herring and another distraction.

Dr. Marcus D'Ayala, who implanted the filter in Ms. Booker, testified unequivocally that he wanted a filter he knew could be retrieved in a patient of Ms. Booker's age. The

11:03:44 Simon Nitinol filter was not an alternative for him given what he -- the type of filter he wanted implanted in this patient.

Yesterday or the day before we heard the testimony by videotape of Dr. Scott Trerotola from the University of 11:04:03 Pennsylvania, and it was quick and hard to catch as he talked fairly fast, but he said, we used to call that filter the Simon Frightenol because it was replete with all of these complications.

Couple of days ago you heard from Dr. Christopher 11:04:21 Morris, the interventional radiologist from Vermont, who has been using Bard filters for years, as well as other filters. And he talked about the many, many complications he and his practice group had had with the Simon Nitinol filter.

Ladies and gentlemen, the Simon Nitinol filter was 11:04:39 not appropriate for Ms. Booker, just as her doctor decided. That is a red herring in this case.

Another red herring in this case is the FDA warning letter. First introduced to Mr. Carr, they wanted to mention this, oh, the FDA has come and slapped you, Bard, for doing 11:05:04 something wrong with regard to these filters.

You'll have evidence back with you. You can look at the warning letter. It is simply not relevant. It is a red herring and it is a distraction. It's meant to divert attention from the fact that the FDA has been intimately 11:05:23 involved in discussions with Bard about these filters for

11:05:28 15-plus years.

Why is the warning letter a distraction? Why is it a red herring?

It was issued in 2015, eight years after Ms. Booker's 11:05:46 filter was implanted. It concerned technical reporting issues. How are adverse events reported. Many of them involved the Denali filter, the latest generation filter where the company makes the filter out of components. Very few of them had anything to do with the G2. And most all of them 11:06:06 were events that had been reported to the FDA, and the FDA said, well, maybe you should have called it this as opposed to call it that. But it was reported to the agency.

None of the violations the FDA suggested had anything to do with a failure to report to the FDA injuries to 11:06:28 patients. No suggestion that Bard did not do what it was supposed to do and tell the FDA every time it learned of an injury to a patient.

The FDA warning letter itself, if you look at page 10, is not actual regulatory action, it's merely a 11:06:50 warning if you don't take corrective procedures to address the issues the agency has cited.

And most important, you heard from Mr. Modra yesterday, and you will see in the letter, if you want to read it, there is nothing in that letter that has to do with the 11:07:09 design or the warnings regarding the G2 filter.

11:07:14 Ladies and gentlemen, I submit to you that, once again, the warning letter is a distraction. It is a red herring, meant to divert your attention from the real issues in this case.

11:07:27 And what are the real issues? They're the ones that Judge Campbell just instructed you on about Ms. Booker's claims. She alleges a design defect. Under the law it is called a strict liability claim or a negligence claim, and you will see the definitions. But they're very similar.

11:07:48 She alleges a warning defect. And, again, under the law there is something called a strict liability warning claim and a negligent warning claim. And you'll see the definitions. They're very similar.

There's a causation element. She has the burden of

11:08:05 proving not only that there was a defect in the product, in the design, or in the warning, but that that defect was the cause of her injuries.

You also are going to hear testimony -- or hear about the evidence concerning Dr. Amer's fault and his role. And

11:08:28 then she has the burden of proving damages.

Let's look first, if we could, at the issue of design.

That's the first question the verdict form will ask you to decide, was the design of the G2 filter defective?

11:08:46 And in making that determination, ladies and

11:08:49 gentlemen, the key issue you will have to address are weighing the risks of the G2 filter against the benefits.

The law is explicit on that. Here is part of the instruction that you were given and that you will have back in
11:09:06 the jury room: To determine whether a product suffers from a design defect, you must balance the inherent risk of harm in a product design against the utility or benefits of that design.

So whether this G2 filter was defective depends on making that calculus, weighing those risks and those benefits.

11:09:36 Let's talk about a document that I think addresses this issue head-on. What are the risks versus benefits of IVC filters? This was the document in 1996, before the retrievable filters were still on the market -- were even on the market, but addressing permanent filters and addressing
11:09:59 IVC filters and deciding how to classify them. The FDA is looking at them.

And the exhibit is 5877.

And the agency is explicitly weighing the risks and the benefits here of the IVC filters.

11:10:22 And what does the agency say? The agency concludes that even though there are life-threatening risks associated with these devices, the disease that they are designed to treat, the disease state, deep vein thrombosis and PE, are life-threatening themselves. And the agency determines that
11:10:48 the risks outweigh the benefits.

11:10:56 And the agency made this determination knowing about the very risks that occurred in this case.

The agency knew about filter migration, and even though the FDA knew that filters, in its view at that time, 11:11:15 migrated 6 to 53 percent of the time, it was still willing to say that the benefits of these devices outweighed their risks.

And with regard to fracture, the agency knew and says in that document, Exhibit 5877, that filters may fracture. That it's been reported at 2 percent of the time to occur. 11:11:44 And despite knowing that, the agency determined that the benefits of IVC filters outweighed the risks.

Why would the FDA make that determination when risks such as those that unfortunately occurred with Ms. Booker can occur with these devices? It's because of the danger that 11:12:11 we've heard about so much, a deep vein thrombosis and pulmonary embolism. These aren't minor conditions. These are life-threatening conditions.

You heard various statistics because the reports are a little over the -- across the board, but as many as 200,000 11:12:29 of our fellow Americans die of pulmonary embolism every year. And if those people at high risk of dying from that disease or the disease state cannot receive anticoagulation, about the only choice left is to give them a filter. And that is why the FDA determines that the risks of these devices are 11:12:57 outweighed by the benefits.

11:13:02 Mr. Lopez just stood up and suggested that these filters really don't have benefits. And they tried to suggest that to you during the course of this case. They brought, first of all, a couple of weeks ago, Dr. Michael Streiff. He
11:13:16 was the doctor from Johns Hopkins who said, well, the studies are unclear as to whether filters had benefits.

But when I cross-examined Dr. Streiff, he admitted quite clearly that he would implant in his own practice a filter in a patient like Sheri Booker. He said that if a
11:13:41 patient had a pulmonary embolism in the last several weeks, just like Ms. Booker had had one the month before, that if a patient was facing surgery and could no longer take anticoagulants, just like Ms. Booker was when she was getting ready to undergo the procedure for her cervical cancer, and if
11:14:03 a patient had cancer, like Ms. Booker did, even he, the witness they brought in to suggest to you filters aren't effective, even he would implant a filter.

Dr. Derek Muehrcke, the plaintiff's own expert, testified that he still implants filters.

11:14:26 They want to tell that you these devices aren't effective. They want to tell you they don't have benefits. And they bring to you experts that implant these frequently in their practices.

You heard a couple days ago Dr. Morris from Vermont,
11:14:45 who said in all his years of using filters, both Bard and

11:14:49 other filters, he's never had a pulmonary embolism in one of those patients.

Further evidence that these devices work.

You also heard him go through all the studies that 11:15:02 are out there that suggest these devices save lives.

Another one of the plaintiff's experts, Dr. Darren Hurst, an interventional radiologist from Cincinnati, he came here early in this trial, and while on the one hand they're trying to tell you filters don't work, 11:15:22 filters don't provide benefits, Dr. Hurst admitted he implanted a Bard filter two weeks ago.

And I also would suggest to you it's a little contradictory to say that the people at Bard acted so egregiously in developing this filter and with such malice and 11:15:44 recklessness that they deserve a punitive damage award being placed against them, and then to bring in an expert that you hired, that you paid tens of thousands of dollars, by his own admission, who says, "I implant Bard filters."

But the fact of the matter, how can they say filters 11:16:03 don't work when all of their own experts implant them and would have implanted one in Ms. Booker.

Perhaps the strongest evidence that filters work is Ms. Booker's own story. She had two pulmonary emboli before she received this filter, and then she had this filter for 11:16:34 seven years with no recurrent PE.

11:16:36 No one has a magic wand to be able to tell what was going on with her filter and pulmonary embolism, but it's telling that in seven years, even though she had had two PEs previously, seven years with the filter and she had none.

11:16:58 You also heard a couple days ago from the chief scientist at Bard, Dr. John DeFord. And he explained the benefits of these devices, even in the face of these risks, even risks that can be catastrophic. This disease is killing people. PE. And you have to have a therapy to treat that.

11:17:24 He's talking about the migration of the Recovery filter here, he says the device is still adding value. It's trying to stop a massive clot.

And you saw that picture of the massive clot in the first Recovery filter migration event. But the device is

11:17:42 still adding value.

In addition to the great benefits of these devices, they're lifesaving benefits to combat a disease that the surgeon general says is a national call to arms situation.

There is a lot of evidence, other evidence I suggest,

11:18:03 indicating that this device is not defective.

And what is that evidence?

First is the extensive, very extensive testing conducted by Bard. Mr. Lopez and his colleagues have tried to criticize that question -- testing quite a bit. But all their

11:18:22 criticisms for the most part deal with the Recovery filter

11:18:25 tests because, once again, they're throwing out a red herring, I suggest, to distract you.

What is pertinent to the device implanted in Ms. Booker is the testing done on the G2. And the testing -- 11:18:39 don't get me wrong, the testing done on the Recovery filter was thorough and detailed, and much of what the plaintiffs say about it is simply not supported by the record and by the reports that the FDA reviewed. But they're not looking at the G2 testing, which is at issue here.

11:19:01 That testing showed that the fracture resistance of the G2 filter was dramatically improved over the fracture resistance of the Recovery filter. Dramatically.

Bard set out to make the G2 more fracture resistant, and both the testing and the statistics, which are important, 11:19:27 despite what they say, support the fact that it was a success. The G2 was much more fracture resistant than the Recovery filter.

The testing shows that the G2 was much more migration resistant than the Recovery filter. And, again, not only the 11:19:52 testing, but the statistics support that.

There were no reports and never have been that we can locate of a G2 filter, as I said, going to the heart and -- migrating to heart and causing a death. There were caudal migrations which, as the FDA has indicated, are generally 11:20:12 minor and asymptomatic events. But there have been no

11:20:17 instances of a G2 migrating to the heart.

Why? Because the redesign of the filter for the second generation succeeded once again, as shown by the testing.

11:20:32 I hope you caught the testimony of Rob Carr, the engineer, when I asked him, how much has Bard spent on testing? He said over the years Bard has spent more than $18 million in testing in developing its filters.

In opening statement, I don't know if you'll remember 11:20:51 this, but Ms. Zaic stood up here and showed you a slide that said Bard spent more to market this filter than it ever spent in research and development and engineering. And that's simply not true.

The evidence -- there's not a single shred of 11:21:10 evidence to support that. And the evidence is clear from Mr. Carr about the massive amounts of money this company has spent to develop.

And that's shown in all the testing. All that testing is included in the documentation that's been admitted 11:21:28 as exhibits. I know, I know, it was boring as can be to sit here and listen to me hand test report after test report after test report to Mr. Carr. But it was important for to you see the extensive amount of testing and work that has been done by this company conscientiously in order to develop this filter.

11:21:54 So, against the background of that evidence, of

11:22:00 research, development, and care, all of which was shared with the FDA, all of which was looked at carefully by the FDA to the point that they had many questions we had to answer to the FDA, what did the plaintiffs bring you to suggest, no, this
11:22:17 design is defective?

And I say what do they bring you, I'm talking about not rhetoric, not arguments, not standing up by a lawyer saying this is a horrible device, this is this, this is that. I mean, scientific engineering evidence of a design defect.

11:22:35 They brought you one witness. Dr. Robert McMeeking.

Dr. Robert McMeeking is a professor, and he has a lot of experience in the academic world.

But I want you to think about what he admitted when I cross-examined him. First of all, he had no opinion as to
11:22:57 comparative rates. He tried to tell you, oh, the G2, it's defective, that design is weak, fragile, it's defective. But he doesn't know whether it has complications more than the Cook filters, more than the Cordis filters, more than any competitive filter. He had no opinions as to how the
11:23:18 complication rates with Bard filters compared to the rates of others.

He conducted absolutely no bench testing.

Remember, he said he did mathematical computations and some computer modeling. And he brought into this
11:23:34 courtroom none of his calculations and none of his modeling.

11:23:40 He said, I did it, trust me, this is what it shows.

He'd never tested an entire filter. I don't know if you remember, but I kept asking him questions because he tested one arm. I kept making this weird gesture, but I
11:23:57 wanted to make the point. He did all his calculations and all his computer modeling of strains on the filter assuming one arm. Not the whole device, but one arm.

I mention that, only calculations and computer modeling, but brought none of his work.

11:24:18 Ladies and gentlemen, he admitted he had never designed a medical device. He's an academic professor and one of -- well respected. But he came in here to tell you that the design of the Bard filter was defective based upon calculations regarding one arm and with no prior experience in
11:24:41 designing a medical device. He had no alternative design. He admitted, "I have not tried to come up with an alternative design."

And, ladies and gentlemen, the plaintiffs have not put up one shred of evidence during the course of this trial
11:25:02 of an alternative design to the G2 filter. Not one. The best they could do is say, well, there's the Simon Nitinol. When everybody else, even their own witnesses are saying, no, we wouldn't us that, we don't want a permanent filter. They did not produce any evidence of an alternative design.

11:25:19 And when you get the Judge's instructions, look at

11:25:22 the definition of a design defect claim, and evidence of an alternative design is important. It's not absolutely required, but it is important. It's an important factor for you to consider: Did they bring in evidence of an alternative 11:25:38 design? And they did not.

But what was the most telling evidence that Dr. McMeeking presented, I think, right the at end of his cross-examination? After talking quite eloquently in that accent I wish I had instead of a southern accent, he talked 11:25:58 about everything wrong with the G2. And then he admitted that six months ago, he was in a courtroom in Indi- -- Evansville, Indiana, testifying for these same attorneys against another filter manufacturer, Cook, saying that their filter was the worst on the market with the most complications.

11:26:20 Ladies and gentlemen, that is their evidence of design defect.

We brought to you Dr. Paul Briant from Exponent. And, yes, his company has been paid some money by Bard because they wanted -- with all of these allegations that 11:26:40 Dr. McMeeking was throwing out, we wanted somebody that we could respect to go and look at these allegations from a very scientific perspective. Because if we didn't think the G2 was a good filter and was defensible, if we thought what Dr. McMeeking said was true, we wouldn't be here. So we 11:27:02 wanted to find out.

11:27:03 And we went to Dr. Briant and his company. And he looked at the assumptions that Dr. McMeeking had made in his testing, and he said those aren't right. Perhaps not surprisingly, given Dr. McMeeking's involvement in litigation 11:27:24 for these same attorneys against various manufacturers, perhaps it is no surprise that the assumptions he made were so biased. He ignored the fact that Nitinol is a unique substance and is superelastic. And in making his calculations, he didn't consider that. In making his 11:27:42 calculations, he looked at only one arm, as I said. Exponent said, you can't do that. You've got to look at the entire filter.

Dr. McMeeking assumed, in an effort to get the highest strains in the calculations he could, that the 11:28:00 inferior vena cava is a rigid structure of the anatomy. It's not. Tissue deforms. It's a human dynamic part of the anatomy. He made an assumption about the anatomy that just is not true.

And he made other assumptions that were very biased. 11:28:21 And what were the results? When you put in the assumptions that are correct, that have the right elastic properties of Nitinol, that have -- considered entire filter and not one arm, look at the results. The red shows the strains that Dr. McMeeking determined at various levels with his biased 11:28:47 assumptions, and the blue shows the strains calculated using

11:28:52 realistic, conservative but realistic, assumptions.

And those calculations show that the forces of strain and stress on these filters are dramatically lower than the one expert they brought to try to say this design is

11:29:10 defective.

We brought to you another expert, a metallurgist by the name of -- a materials engineer by the name of Dr. Audrey Fasching. She is the only witness that's testified before you who ever actually examined filters, including Ms. Booker's

11:29:33 filters.

And she told you that of the 29 filters, fractured filters that she has examined as a part of her work, she could find no correlation, no pattern. It's not like the same thing was happening in each filter.

11:29:51 Every different filter was a unique event.

And she is the only witness that testified in this case who actually examined Ms. Booker's filter after it had been removed in its fractured state and said she could find no evidence of a design defect.

11:30:15 I submit to you that the plaintiff's interventional radiologist, Dr. Hurst, essentially admitted that these things are not designed defectively. He testified at one point in a very candid admission, I thought, that the G2 complications he's seen are unintended consequences with this filter.

11:30:37 The plaintiffs have tried to tell you there need to

11:30:40 be comparative complication rates in an IFU. Dr. Hurst admitted he's never seen that before in any IFU.

And importantly, and I think you'll remember my bad experience, shared by Mr. O'Connor, at math, but he admitted a 11:30:59 1 percent complication rate with an IVC filter is probably pretty good. Those were his words. "Probably pretty good."

All of the evidence I've seen, all of the evidence I've seen the plaintiffs present, and all of the evidence we have in our internal files indicate that the G2 complication 11:31:22 rates in every area are well less than 1 percent.

Perhaps most importantly, the numbers that were presented by Mr. Modra yesterday.

Now, these numbers, as he admitted freely, they are not perfect. They are not exact. But they are the best data 11:31:51 available. You heard how comprehensively Bard investigates every adverse event regarding its filters reported to it. Every single adverse event. Whether it's reported in the medical literature, whether it's a doctor calling, whether it's someone calling to the hotline in Covington, whether it's 11:32:13 a sales representative overhearing something in the hospital cafeteria, every single event is investigated. Every single event, even if it's not, for whatever reason, reported to the FDA, is trended in these numbers.

And what do these numbers show? Through December of 11:32:37 2016, 130,000 G2 filters sold, with 312 fractures reported and

11:32:51 207 migrations. And look at how low those percentages are.

Again, I'm not up here trying to tell you that's the gospel truth. No one knows for sure. There are going to be some reports or some events that aren't reported. There are 11:33:09 going to be some, although I don't think it would be many, filters that are sold, but given their price -- despite their price, not implanted. But it's the best data we have.

Assume it's wrong. Assume that because some events haven't been reported, because some filters sold weren't 11:33:30 implanted, that the rate is twice that amount. It's still below 1 percent. Even if the data's so wrong that the number -- the percentage is three times greater than shown there, it's still below 1 percent.

And as Dr. Hurst told you, the plaintiff's own 11:33:55 expert, a complication rate with one of these devices, which he implanted a Bard device just two week ago, is "probably pretty good."

Sometimes all these statistics are confusing to someone obviously as deficient in math as I am, and I like to 11:34:17 try to convert it to see what it means in the real world. And what it means is that of the 130,000 filters, G2s that Bard sold, 99.76 sold had had no reported fractures. 99.84 percent sold had had no reported migrations. 99.76 sold had no reported perforations.

11:34:50 And I forgot to mention one other thing here. This

11:34:53 is, again, evidence. Look at the Recovery filter, RF048 was the catalog number for the Recovery filter. Look at that. Look how much higher the Recovery filter fracture rate was than the G2. Why? Because the company's efforts to redesign
11:35:15 the device to make it more fracture resistant worked.

Look at how much lower the migration rate is. Almost half as low as the Recovery filter. And as we've heard all the time over the last three weeks, most of migrations with the G2 were caudal, downward, and not the much more dangerous
11:35:37 cephalad migrations with the Recovery filter. But even then with those caudal migrations, the migration rate of the G2 is almost less than half that of the Recovery filter.

And what about the Society of Interventional Radiology, how do Bard's rates, well less than 1 percent,
11:36:03 compare to the medical community's expectations? And how do we know the medical community's expectations? You heard Dr. Clement Grassi on Tuesday, from Boston, he was the chairperson of the Standards and Guidelines Committee for the Society of Interventional Radiology in 2001, when they
11:36:24 developed the first guidelines ever published.

And what did those guidelines show? And see here, he is the lead author as the chairperson of this committee. And these guidelines were published in the Journal of Vascular and Interventional Radiology.

11:36:45 They recognized, the medical community recognized, it

11:36:49 was known in the medical community that IVC filters would result in a complication causing death a certain percentage of the time.

Perhaps more important for this case, the medical 11:37:05 community recognized that IVC penetration occurred, that migration occurred, and that fracture occurred. And they looked across the literature and saw rates, Dr. Grassi's committee, that ranged from zero to 41 percent on penetration, zero to 18 percent on migration, 2 to 10 percent on fracture. 11:37:34 And despite that knowledge of the medical community, interventional radiologists were still implanting these devices based upon determining that their benefits outweighed the risks.

And I ask you to look at the Bard statistics, the 11:37:54 best available data as to the complication rates for Bard filters, well less than 1 percent, and see how they stack up against the expectations of the medical community.

Now, in determining whether there is a defect in the design of this filter, you also need to look at the regulatory 11:38:16 history.

And this is a statement of Georgia law that was contained in the instructions given to you by Judge Campbell that you'll have back in the jury room: You may consider proof of a manufacturer's compliance with federal or state 11:38:30 safety and non-safety standards or regulations and

11:38:34 industry-wide customs, practices or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the
11:38:51 manufacturer knew or should have known.

Ladies and gentlemen, I submit to you the record in this case, and the evidence you have seen shows a long history of Bard complying with federal regulations in the design and development of not only the G2 filter but, before that, the
11:39:10 Recovery filter.

The FDA guidance, you heard Donna-Bea Tillman, the former FDA official, talk about this. Dr. Tillman. This is the guidance published by the FDA suggesting to manufacturers what needs to be done to develop and market a filter. And
11:39:31 Bard followed that guideline.

There are frequent communications that have been introduced showing that Bard was in communication with the FDA, that Bard was telling the FDA about complications it was seeing in the field with its device. Talking to Bard about
11:39:54 the tests that were being performed.

You saw when the Recovery filter 510(k) was initially presented, Mr. Carr explained how the FDA sent back a letter with 17 detailed questions about the testing, to which we responded.

11:40:10 When we submitted the G2 application, the agency had

11:40:15 a number of other questions specific to the testing that we had to respond to and satisfy the agency.

There were four separate 510(k) submissions related to the G2. Four. Each one involved a package going to the 11:40:35 agency. All of that is in front of you. Each time we had to comply with the rules, send the FDA all of this information. Each time they reviewed it, they would ask questions, and four different times the FDA cleared the G2 filter.

We have internal FDA memos. You saw a number of 11:40:58 those obtained through the Freedom of Information Act.

This is with regard to the G2 submission, where we're seeking clearance for the G2. The FDA is looking at our bench testing and they decide they want additional information.

They're looking at our animal tests and they note 11:41:25 that they see no safety issues identified in those tests.

They analyzed the bench testing ultimately and decided that it is sufficient to show substantial equivalence.

And then the work with the FDA doesn't stop when the agency clears the device. You'll see the evidence that it 11:41:56 continues all along. Dr.- -- Mr. Van Vleet, who was here Monday, testified that Bard had a big meeting with the FDA in January 7 of 2010 to discuss the filters.

And at that meeting -- and the PowerPoint has been introduced here as evidence -- Bard presented to the FDA all 11:42:19 its internal data on complications as of that date with both

11:42:26 the Recovery filter and G2 filter.

Bard was also fully transparent with the FDA regarding the caudal migrations they like to talk about so much.

11:42:47 The evidence shows that Bard specifically told the FDA about how its analysis of caudal migrations exceeded the threshold in the DFMEA at first, and they went back and reanalyzed it. This was no surprise to anyone. This was not something that was hidden. It was specifically talked about

11:43:10 with the FDA.

And then there's the EVEREST study which they've talked so much about. But, again, they didn't tell you the whole story, ladies and gentlemen.

All of those events, adverse events reported in the

11:43:26 EVEREST study, were asymptomatic, with one exception. All of them. That's what the report showed. That's what the data shows. And what they like to overlook is the fact that all of that data, every bit of it, was submitted to the FDA, and the FDA cleared the G2 for retrievable use in 2009 with all of

11:43:52 those EVEREST study adverse events in front of them.

Ladies and gentlemen, I suggest to you that this record shows that Bard complied with the FDA in the design and development of the G2, and that's an important factor under the law for you to consider when determining whether the

11:44:15 design is defective.

11:44:17 Now, what did the plaintiffs primarily rely on during the course of this trial to say, no, no, no, there's a defective design?

11:44:28 I submit to you, ladies and gentlemen, it was two documents that we saw almost on a daily basis here. But even when presenting those documents, they didn't tell you the whole story.

I thought one of the most telling bits of testimony in this entire trial came from Ms. Booker herself when she

11:44:48 corrected Ms. Helm, incorrectly, saying, when shown a medical record, she wanted to see the entire record. Understandably. And she said, "I've learned from this trial that you need to make sure you see everything."

Those were her words. And, ladies and gentlemen,

11:45:10 she's right.

How many times did we see this report where, under the DFMEA, Natalie Wong has determined that the rate of caudal migration is unacceptable. How many times did we see that?

But you need to see everything. Everything. What

11:45:39 they didn't show you is page 4 of that same exhibit. Ms. Wong, when she's conducting that analysis, is doing so based on 13 reports. This is very early in the development of the G2 filter.

They want to tell that you we hid from the FDA --

11:46:00 which we didn't, I showed you the memo -- and that we hid from

11:46:04 the world that the caudal migration rate was unacceptable. Simply because, when you look at the whole story, she was analyzing 13 reports of adverse events in the early days of the agency -- I mean, of the sale of the product.

11:46:22 Ladies and gentlemen, I submit to you that is not the whole story and that is not seeing everything.

It didn't end there.

How many times did we see this chart? Over and over and over. Suggesting that the G2 had much more

11:46:39 complication -- many more complications than the Recovery filter.

Well, I pointed out with Dr. Hurst, I believe, finally, let's look at the whole story here. Let's look at page 2, where it is very clear that this only involves 56

11:47:01 total adverse event reports.

And look at the percentage, the complaint rate, how miniscule it is. That's the whole story. Not one chart that they like to misinterpret, but the whole story is this was a careful analysis by the company when it was constantly

11:47:23 monitoring the performance of its device based upon 56 adverse events.

And Dr. Hurst said, well, you know, they determined that rate by how many are sold, and probably all of them that are sold are not correct -- or not used, and well, you know,

11:47:46 there's an underreporting, not all of the bad events are

11:47:49 underreported. So I sat here and scribbled some math, and this is what that math shows: There were 56 events reported as of that time. Let's assume Dr. Hurst is right and let's double the number of adverse events and say that because of
11:48:12 underreporting there were 112 adverse events.

At that time there were 100,000 G2 units sold. He said they all weren't implanted. Well, let's assume only 60 percent, a very low number, were implanted.

Even with those numbers, trying to adjust for
11:48:33 Dr. Hurst's challenges, you come up with a rate, complaint rate of only .18 percent. Far below the 1 percent threshold that Dr. Hurst himself said is probably pretty good.

Ladies and gentlemen, I submit to you that taking all of this evidence together, looking at both sides of the story,
11:49:04 the evidence shows that the benefits of the G2 filter -- we're not talking about the Recovery filter, we're not talking about the Simon Nitinol filter -- the benefits of the G2 filter implanted in Ms. Booker outweighed these small risks.

Now, the second claim the plaintiffs make is warning.
11:49:29 They claim that we did not warn. But they never want to show you the instructions for use that were sent out with every single device sold by the company.

Here's the standard. This is what the instructions of Judge Campbell tell you you've got to assess in determining
11:49:49 whether there was a failure to warn or to provide an adequate

warning.

These warnings specifically warned about fracture. Fracture is a known complication of vena cava filters.

That was known by the FDA in 1996, when it did its risk/benefit calculus. That was known by the SIR in 2001, when they published their guidelines.

Potential complications also include movement or migration. Perforation.

Again, all risks known to the medical community.

Well, how did they attack that?

Dr. Hurst came up here on the stand and said, you know, Bard failed to warn about the severity of these risks, just how severe they could be.

Ladies and gentlemen, look at what Bard specifically reminded physicians in the IFU with every G2 filter: All of the above complications have been associated with serious adverse events such as medical intervention and/or death.

The risk-benefit ratio of any of these complications should be weighed against the inherent risk-benefit ratio for a patient who is at risk of pulmonary embolism without intervention.

In other words, Bard's warning doctors there is a risk/benefit analysis that you, as the treating physician, have to conduct here because we know, as the medical community knows, that there are risks with these devices, but we also

11:51:37 know, as the medical community knows, that the risk of pulmonary embolism without protection can be a fatal event also.

The G2 filter instructions were comprehensive, and 11:51:53 they covered every single complication that occurred here. And perhaps recognizing that, the plaintiff said, well, you should have warned us that your complication rates were higher than other devices.

First of all, they have no evidence, none, that our 11:52:11 rates are higher than other manufacturers' complication rates. There has not been a single bit of evidence to that effect in this case. There has been a mention of this study or that study, but there have been mentions of many studies that show Bard rates are very low.

11:52:27 And you heard Dr. Feigal, the former head of the device area of the FDA and a practicing epidemiologist, come in here and say there is no medical literature that allows you -- or studies out there that allows you to reach a conclusion about comparative rates of filters.

11:52:45 And certainly you can't use the MAUDE database. The FDA tells you that, to do that. How could we possibly have warned about something that there's no evidence of and certainly no reliable evidence of?

But, ladies and gentlemen, they paint different 11:53:07 reality when they say, well, it's not just the IFU, Bard could

11:53:10 have done other things; Bard didn't do anything.

Ladies and gentlemen, Bard did things. Bard acted responsibly.

Let's look at the Recovery filter situation with the 11:53:20 migration death reports. Bard sent out two letters, and those are in the record. This one was developed in consultation with the FDA, warning doctors that the IFU had been revised and to mention fracture and additional information about migration.

11:53:43 In May of 2005, again in consultation with the FDA, Bard sent out a letter to all the doctors in its customer database, every one that they had record of, specifically telling them that there had been reports of deaths from the migration of the Recovery filter. The notion that Bard stuck 11:54:06 its head in the sand and did nothing when adverse events were happening is simply not true, and the record shows otherwise.

The doctors were warned with the IFU, and when appropriate the doctors were warned with special letters. And the evidence on that is clear.

11:54:28 Ladies and gentlemen, briefly, the plaintiffs must show not only a defect either in the design or the warning, but a causal connection between that defect and the injuries.

You'll remember Ms. Booker's medical history, which culminated in heart surgery in July of 2014.

11:54:56 Think about the evidence you've heard during this

11:54:57 trial. Did the filter cause the heart surgery?

Doctors had more than five years to discover that fractured strut when it was next to the IVC filter and not in the heart.

11:55:12 Once in the heart, that strut was encased in tissue and was not moving.

You heard Dr. Sobieszczyk yesterday say he's had patients in that situation where he's not removed the fragments.

11:55:29 The testimony is absolutely clear that the filter did not damage Ms. Booker's tricuspid valve, which was a major reason for the surgery, but that the actions of Dr. Kang in trying to remove that strut, going back and forth through that valve, is what damaged it.

11:55:50 Dr. Kang admitted that Ms. Booker is the only patient in his practice that he's ever tried to treat to remove a fragment of a device from the heart. And he admitted that it was his procedure, not the filter, not something else, that damaged the tricuspid valve.

11:56:12 Dr. Patel, her treating cardiologist, admitted again also the damage to the tricuspid valve clearly was attributable to Dr. Kang's procedure. He also reported no symptoms attributable to the strut in the heart.

And then there's a question as to even if you thought

11:56:35 somehow the IFU or other warnings were inadequate, how could

11:56:39 that be a causal factor in this particular case?

Here's Dr. D'Ayala, who implanted the device. He did not establish any link between warnings and what he did. He never testified that he read the IFU. He only said it was 11:56:56 available to him. He didn't seem to specifically recall having read it. He was aware of the very risks that occurred here. And he can't recall any specific conversations he had with the Bard sales representative or anyone else from Bard regarding the G2 filter.

11:57:15 How is there anything as far as warnings given or not given by Bard that could have had some sort of causal link with the injuries here.

And furthermore, there was the testimony of Dr. Scott Trerotola, who probably put it best as to why different 11:57:37 warnings would not have mattered. As he says, "I take the brochures and throw them in the trash." I'm sure there are people, my client, that would not like to hear that, but that's the reality. Doctors are scientists. They're relying on medical literature, not marketing and promotional.

11:57:56 Then there's the question of Dr. Amer's fault. Or Dr. Amer's fault.

Remember the photograph, you saw it again yesterday, in March of 2009? Well, they're saying it was a diagnostic radiologist who looked at that and not an interventional 11:58:13 radiologist.

11:58:13 Well, I'm a lawyer from Atlanta, Georgia, and you are good men and women from Phoenix, Arizona, and we can look at that and see something's not right.

There is an arm pointing in the opposite direction. 11:58:28 It's apparent. I don't care if you're an interventional radiologist, if you are a diagnostic radiologist, or you are a 16-year-old teenager, you can look at that and say something's not right. This was a missed opportunity. This was an opportunity when there was no strut in Ms. Booker's heart, no 11:58:50 strut. And somebody could have seen this, somebody could have reported it, and somebody could have retrieved that filter percutaneously, just like Dr. Kang did later, but before the strut went to the heart.

Lastly, ladies and gentlemen, I want to talk to you a 11:59:06 minute about damages.

I hate to even mention damages because in my heart of hearts I don't believe you should reach that question. And you only reach that question if you first find liability against my client.

11:59:20 But I ask you to look at the instructions and remember what Judge Campbell just instructed you. Under Georgia law, which applies here, the law seeks to ensure that the damages awarded are fair to both parties.

This is not a sweepstakes or a lottery, it is a court 11:59:45 of law, and the damages awarded should be fair, if you even

11:59:48 get to that point, to both parties.

And then let's talk about punitive damages. They are not only asking you for compensation, despite, in my view, not having shown a defect, for her actual injuries and costs. 12:00:04 They're seeking to get you inflamed to punish my client.

Under Georgia law, it's not by a preponderance of the evidence. It's not does the evidence barely show more probably than not Bard deserves a punitive award. It is by very exacting standard, clear and convincing evidence.

12:00:28 And you -- they have to show you by clear and convincing evidence that Bard was guilty of willful misconduct, malice, fraud, wantonness, oppression, or the entire want of care that would raise the presumption of conscious indifference to consequences. This isn't a walk in 12:00:49 the park, this is an exacting standard because this is a drastic remedy.

Ladies and gentlemen, I could sit here for five hours -- and I won't, I promise -- and tell you all the reasons I believe this evidence would never justify a finding 12:01:04 of clear and convincing evidence to award punitive damages against my client, but I think the biggest testament to that fact are the people at Bard. You saw them. We brought them, both present and former employees involved with this device. Andre Chanduszko, Mike Randall, Chad Modra, Shari O'Quinn, 12:01:25 Rob Carr, Natalie Wong, John Van Vleet. These are biomedical

12:01:31 engineers, biologists, regulatory specialists, clinical affairs specialists. Men and women who have devoted their entire career to the development of medical devices to save and make the lives of all of us better.

12:01:45 And I submit to you, you did not hear one bit of evidence from the people here, only from the questions being asked but not from the people on the stand, that showed you or even suggested the sort of conduct they're claiming deserves a punitive award here.

12:02:07 There's another thing in the statistics, yes, but another point that I think makes the point as to why there's no evidence justifying punitives here. You will see from this chart that Bard now has had six generations of retrievable filters. The company didn't spend $18 million on research and

12:02:32 development for nothing. Every time it has made one of these, since the first revolutionary retrievable filter, the Recovery filter, it has moved on to improve, and improve, and improve. There was the Recovery, then the G2, then the Eclipse, then the Meridian, then the Denali.

12:02:50 And you look at the chart, Exhibit 5874, and you see the complication rates. They go down every time.

This company is constantly working to improve this device, a device that, even in the early iterations, doctors determined that the benefits outweighed the risks. That it's

12:03:15 constantly improving it. Is that malice? Is that an entire

12:03:20 want of care by clear and convincing evidence? I submit to you, ladies and gentlemen, it is not.

You see the rates. They go down every step.

12:03:37 Ladies and gentlemen, you're going to be given a verdict form, and during your deliberations you're going to be asked to fill out this verdict form.

And I would like to suggest to you, respectfully, that based upon the whole story, all of the evidence you've heard, not just the arguments of counsel, not just page 16 of

12:03:55 a document instead of the entire document, that your answers, the evidence would justify, should be as follows:

Do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the strict product liability design defect claim?

12:04:11 No.

Do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the strict product liability failure to warn claim?

No.

12:04:27 Do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the negligent design claim?

No.

And do you find by a preponderance of the evidence that Bard is liable to Ms. Booker on the negligent failure to

12:04:42 warn claim?

12:04:44 No.

And then there will be other questions for you to address if, in your considered judgment, you don't agree with the answers that I suggest.

12:05:03 Ladies and gentlemen, we are approaching the time that jurors like the best in a trial, when all the lawyers have to sit down and shut up.

The plaintiff gets the last word now, the rebuttal argument, because the plaintiff bears the burden of proof.

12:05:21 And I must tell you that as a lawyer who cares passionately and probably has irritated you at some point during the course of these three weeks with my zeal, and I apologize if I have, but as a lawyer who feels passionately about his client and the case, this is the hardest moment for me in a trial because

12:05:41 I can't say anything else.

They get the last word because they have the burden of proof. My hands are tied. I have to sit over there, and I think Mr. O'Connor is going next, and no matter what he says, no matter how inflammatory it is, no matter how much I believe

12:06:00 the evidence does not support it when you look at the whole story, I can't say a word. And that's hard.

But I would ask that you think about the evidence I've shown you. Think about the exhibits I've pointed out. Think about the testimony you heard. And when you go back to

12:06:17 the jury room and you're thinking about something Mr. O'Connor

12:06:20 says, think -- say to yourself, what would Mr. North say in response? What would Bard say? Because when you look at the whole story, I suggest to you it's a different picture than you'll hear from Mr. O'Connor.

12:06:33 Ladies and gentlemen, I recognize this is a hard case. We all want life to be risk free. Nobody wants something like what happened to Sheri Booker to occur.

Every time we put our kids on the school bus, we want it to be risk free. We want nothing to happen. But

12:06:56 unfortunately there are risks.

Every time we give our teenagers the key to the car, we want it to be risk free. But it's not. There are risks.

Every time we get on an airplane, we want it to be risk free. But it's not. There are risks.

12:07:15 The men and women, the engineers at Bard want to design a totally risk free filter, and they strive every day, as the data shows you, to do so. But just like every other manufacturer in this area of filters, they have not yet succeeded because no matter how hard we try -- they try, no

12:07:36 matter how hard we all wish for our lives and for our children, there are risks that cannot be avoided.

But I submit to you, ladies and gentlemen, that the evidence here is clear that the benefits of the G2 filter outweigh those risks. And as difficult as it is to accept, it

12:07:57 is more important to save lives against a deadly disease state

such as pulmonary embolism than not to have devices like the G2 on the market to do so.

So, ladies and gentlemen, now I have to sit down. They get the last word. I ask you to keep remembering the whole story. And once you get back to the jury room and once you look through all of this evidence, I will ask you, as men and women and members of a responsible jury, to please return a verdict for my client, Bard.

Thank you.

THE COURT: All right. Thank you, Mr. North.

Mr. O'Connor, your rebuttal.

The court reporter has asked that we all stand for a minute. Let's do that.

Thank you.

Mr. O'Connor.

MR. O'CONNOR: Thank you, Your Honor. Members of the jury.

Mr. North stood up here and he said that evidence about the Simon Nitinol filter, the Recovery filter, are red herrings. And of course Bard doesn't want to talk about those two filters because those two filters for Bard are an inconvenient truth. Because they're predicate devices. And that means that Bard has to show substantial equivalence. And that's somethings that Bard can't show, and they knew they couldn't show it. They've known it early on. They knew it

12:10:19 within moments when the G2 was released to the market.

Greg, show slide 18.

And depending on where we're at in this trial and what testimony's going on, they either want to walk away from 12:10:38 their own information or they want to embrace it. But the fact of the matter is, is that the -- Bard was aware that the G2 was worse than the Recovery in just about every failure mode.

You can take it down, Greg.

12:10:56 And they just stood up here, Mr. North, and he talked about transparency. Transparency.

And why is it today in this trial is the first time anybody's ever been told that the Simon Nitinol filter was the Frightenol filter? If they knew that, they should have been 12:11:21 telling people.

But the fact of the matter is that Bard believed the Simon Nitinol filter was a safe filter. And that's why in 2005 the medical director, Dr. Ciavarella, when he walked into his office one day and he was hearing about complaint after 12:11:36 complaint after complaint of the G2, sent out an e-mail, an e-mail where he was very concerned, and he asked the question, why wouldn't physicians be using the Simon Nitinol as opposed to the G2, which has virtually no complaints?

So as we talk today, and we talk about things like 12:12:10 statistics, those statistics, those numbers are people and

12:12:14 they're human beings. And this comes from a company that got cited, a letter of warning from FDA, because they didn't know the difference between a serious injury and a malfunction.

And they want to talk about asymptomatic, and that's 12:12:33 fine. Because the evidence in this case has shown that they -- that may perhaps be the most dangerous problem with the G2 filter, is that it goes through not just one -- the thing about this filter, the thing we haven't seen any statistics on are how many patients had the entire cascade: 12:12:53 The migration, the tilt, the perforation, and the fracture.

They don't want to do a study on that because they know, no matter how they slice it, whether they listen to their own expert, Dr. Tillman, who's telling us MAUDE data is unreliable, or they want to impress the they FDA that they 12:13:19 have some type of statistic based on unreliable evidence, they don't want to do a study on something that they know. And they know the G2 is more dangerous than any filter that's ever come out on the market because of the cascade. Because that filter just doesn't do one failure, it does all the failures.

12:13:42 And while they don't want to talk about patients, they just want to talk about numbers, these numbers have names. And one of them is Sheri Booker.

And Sheri Booker is now a victim of what Bard didn't want to tell anybody about what they knew all along, that this 12:14:10 G2 filter had every failure mode and it would do that inside

12:14:16 of patients.

Now, what this case has shown us is a company that's divided in two sides. There is --

Greg, go ahead and put up Exhibit 4327.

12:14:34 First page, please. Can you put up the entire first page.

This is Exhibit 4327. Take a look at it when you go back today.

This is a monthly report that the people on top, the

12:14:56 suits, if you will, get. The people who make decisions about the company. The people who make decisions and are looking at sales on a regular basis.

And this is in February of 2006, where you know from the evidence the G2 filter has been on the market since August

12:15:14 of 2005.

And what went to the suits was information about the filters that they didn't share with anybody. They kept it to themselves. What they knew about the G2 filter was it was never ready to go to market.

12:15:37 Greg, go to page 8, I believe.

No, back up. I'm sorry. I want to go to the page where they talk about the testing.

After the G2 is on the market, it dawns on the people at Bard that they needed to do a caudal migration failure

12:16:08 investigation, and they had to determine a way to design -- a

12:16:13 way to investigate the root cause.

And it wasn't until then that somebody got the idea that maybe, maybe they should develop a test to evaluate caudal migration resistance, because what Bard knew was caudal 12:16:27 migration, the filter going down, was the beginning of this cascade of tilt, fracture, perforation, and the entire cascade.

And the people in Bard knew that.

The people in Bard were well aware of that.

12:16:47 Go to page 8.

Because what was happening to the people, the presidents and the vice presidents that they were keeping away from doctors, they were keeping away from the sales force, is that they were watching closely all the adverse events that 12:17:02 were coming across their desks. And they were seeing quickly how this G2 was failing. And the things it was doing to patients.

They knew back in 2005, 2006 that someday they were going to have to face a Sheri Booker and many, many more, 12:17:21 because all these patients who they just saw in one month, they kept getting monthly reports, monthly reports, report after report after report. And so all of a sudden they had to make some decisions.

They started desperately trying to figure out, well, 12:17:43 let's decide what the difference between a malfunction and a

12:17:46 serious injury is. And not only that, let's make sure that we're not counting asymptomatic. But they knew. They knew this filter should have never been put on the market in the first place and history repeated itself. Because while they
12:18:05 don't want to talk about the Recovery filter, it is so important to this story, because you remember Dr. Asch. He is the doctor that they promised, they absolutely promised that they were going to do a long-term clinical study. And they broke that promise.

12:18:23 So why stop now. Because, you know, there was such a risk to the market, they wanted that market share so bad, there wasn't time to put patient safety first because if they took the Recovery off with nothing there, that might hurt them. It might hurt their reputation. So they had to come up
12:18:41 with a plan, they had to come up with one quick. So they had the G2.

And that sales brochure that Dr. Trerotola threw away told doctors that this was new and improved stability, centering, and resistant to fracture. And that's what they
12:19:01 did. Knowing that they never learned the lesson from Dr. Asch. Because Bard made a choice at that time and the choice was this: Get it out there and get it out there fast. Get it out there the easiest way we can. Keep these things out in front of these doctors. Don't tell them what we know,
12:19:22 and have them keep buying. We will deal with it later.

12:19:30 And that's what happened.

They didn't do a clinical study. They didn't do one until they absolutely had to.

And listen to what they said today. The failures in 12:19:39 the EVEREST study were asymptomatic. Asymptomatic.

Sheri Booker beat cancer. She is cancer free. But you know what she's not free of? She's not free of Bard. Because every day, every minute, Sheri Booker has to think about that Bard strut in her vein. And you know what? 12:20:02 Sheri Booker was asymptomatic at one time too.

But Bard made a decision, and they talked and made calculated choices. They decided rather than doing the right thing and stop the sales, knowing what they knew in January, that they hadn't even tested, much less for caudal migration, 12:20:27 knowing that they were testing on patients, they made a choice. And that choice was to keep selling. Keep selling because we will deal with the problems later. And they made a choice that they would rather pay what it takes to come to Arizona for a trial than do the right thing to stop the sale 12:20:48 of the G2 filter and stop the injuries, the maiming, and the deaths. Because they figured somehow if they did it this way, they might not have to face anybody.

But now they are. They have to face Sheri Booker.

And look at it the way they have approached this 12:21:15 defense. They have paid experts over $1 million. What if

12:21:23 they would have taken that money and asked Dr. Briant to please do a root cause analysis. What if they had taken that money and said, Dr. Fasching, you have been with us for so many years, stop criticizing Dr. McMeeking. Maybe we should
12:21:40 understand what Dr. McMeeking has to say because what Dr. McMeeking came in and told you is this is basic engineering 101.

And it's not appropriate to test to get the results you want so you can later show the FDA, look, this thing
12:21:54 passed all of our tests. What you have to do with patient safety is more important to you than money profits? You have to test for the worst case scenario. So they hired an expert, Paul Briant, to come in here and criticize Dr. McMeeking for doing exactly that.

12:22:14 Think about this for a moment. Think about this. Dr. McMeeking was exactly right, wasn't he? He showed from basic engineering analyses, basic engineering calculations, that this filter, the G2, would not stay in place.

He showed through basic engineering that they had no
12:22:33 result orient in mind, other than to test for the worst case scenario to protect patients; that if they migrated they would tilt, if they tilt that they would perforate, and if they perforated they would fracture, and if they fracture they would go to places that the medical community may have never
12:22:51 seen before.

12:22:54 And they blame the FDA. When they want the FDA to be their friend, they're their friend. But they blamed the FDA yesterday, saying that the FDA was vague and ambiguous about what is the difference malfunction and serious injury.

12:23:12 I would suggest Bard was well aware if this filter was malfunctioning in patients, that was a dangerous thing. And what they should have done is said stop. But they didn't.

So they also blame the doctors. And I'll tell you, that probably is as much a betrayal to the medical community 12:23:40 as what they did to Dr. Asch. Because these are the people they market to, the interventional radiologists.

But they knew, they knew in 2006 what was happening to these filters. And they had a policy, if you remember from Mr. Modra yesterday, they didn't share that with sales. And 12:24:00 you know why? Because sales had to develop relationships with doctors. Those relationships were built on trust. And if the salespeople knew, like Mr. Orms who you saw in video, they would disclose to these doctors, "I'd be careful, Doctor, this thing goes on to do horrible things."

12:24:18 So if you think about this defense where they're blaming Dr. Kang, they're blaming Dr. Amer, they're blaming these doctors even though they never sent out one of these e-mail blasts or Dear Doctor letters saying stop using the G2, or if you have a patient bring them back in and bring them now 12:24:36 and here's what you need to look for. They never did.

12:24:39 And they want to blame them. They want to blame these doctors for things that no doctor could have possibly have known about, but Bard was well aware of.

And they want to say that somehow what Dr. Kang did 12:24:51 or Dr. Amer did somehow caused injury to Sheri Booker.

Now just let's think about that. Because to get to where they want to be, that means all these doctors should have known that these G2 filters were killers.

But Bard would never tell that to anybody.

12:25:12 So they come in here and they want to blame a doctor. Well, you should have known. We didn't tell you, but you should have known if there was a tilt. You should have known to look for a strut that might be out of position.

They didn't tell them that. They didn't tell them 12:25:27 because, you know what, Doctor, if you see that, even if your patient is asymptomatic, that is dangerous because we've seen it, we've been seeing it every month, Dr. Amer, Dr. Kang, four radiologists. We've been seeing it long before this patient came to you, that our filters cause serious harm.

12:25:49 And you know what, it would have been simple. 2006, send out the Dear Doctor letter, send out a Dear Colleague letter, whatever they wanted to do. But all they were really communicating with were doctors that were using this.

Why didn't they blanket the entire medical community 12:26:06 and tell them, be on the lookout for this incidental finding,

12:26:10 this is dangerous. If you don't catch it, your patient may wind up in a hospital one day undergoing a procedure where her heart has to stop and she has to be subjected to a risky procedure, and we're going to -- they didn't say that.

12:26:38 And so now they want to the blame Dr. Kang, Dr. Amer and four radiologists for something they knew.

The truth of it is this: Bard wanted money and they wanted money bad. And so, you know, when they talk about risk/benefit, they made a choice. Their choice was, let's put

12:27:02 all the risk on the patients. We'll deal with it later. And if we get sued we'll hire experts, we'll have them working for us, we'll pay them millions of dollars, and we'll have them criticize everything their experts say.

THE COURT: Mr. O'Connor -- sorry -- as you asked me

12:27:21 to do, five minutes.

MR. O'CONNOR: All right.

The statistics have names. And there's more of them out there. They call them asymptomatic. But you know what, these asymptomatics have names.

12:27:59 And you're going to go back and you're going to deliberate. And I can tell you this: Bard -- the FDA couldn't stop Bard. They had no reason to. It's an honor system. They relied on what Bard said.

You, you folks have seen the inside story. And

12:28:20 that's why we have a jury. And that's why we have Arizona

12:28:24 juries. Because it's now you. It's in your hand. You can stop this. And you can stop this with your verdict.

You can let them know, don't make that type of risk decision where you're going to let these patients go have 12:28:41 these surgeries, almost kill them, we'll see you in court. Let them know that doesn't happen here in the State of Arizona.

We expect corporate citizenship in this state, and you know what, the only way they're going to know that is if a 12:28:55 verdict gets to the corporate room, to the corporate headquarters, and if the officers that were looking at these issues back in 2006 now have to deal with a large verdict and a verdict that not only compensates Sheri Booker for what she has to think about every minute of her life, but a verdict 12:29:18 that will punish Bard and tell them to stop and let them know this will never be tolerated in our state, and this jury in Arizona is going to do something that will protect patients all over the country from this type of behavior.

That's the only way they will stop.

12:29:42 And that's up to you.

Thank you.

THE COURT: All right. Thank you, Mr. O'Connor.

Ladies and gentlemen, as we mentioned, we're going to swear two bailiffs. Those will be the individuals who can 12:30:00 communicate with you during the trial. Nancy should walk

12:30:03 through that door about now.

All right. Would you please raise your right hand.

(Bailiffs sworn.)

12:30:36 THE COURT: All right. Ladies and gentlemen, you can take your notes with you. We will be bringing the exhibits back and you'll get the instructions on the exhibits. We'll send a set of the instructions back as well. And we will excuse you to deliberate.

(The jury exited the courtroom at 12:30.)

12:31:10 THE COURT: Please be seated.

All right. Counsel, did you have comments you wanted to make on the verdict form?

Oh, Nancy, let's not give them the verdict form yet. We're going to have a discussion.

12:31:25 Go ahead, Mr. Stoller.

MR. STOLLER: Your Honor, very briefly. But I just want to reiterate some of the things we talked about before. We don't think that E is necessary. I actually think it's -- again, I think it's confusing, and I don't think it will

12:31:39 provide us evidence or information at the end that we're going to be able to make any real use of.

If they answer -- obviously they're -- in order to get to there, they're going to have to answer yes to one of 1 through 4. As we discussed before, I think they'll come up --

12:31:54 based on the instructions, they should come up with their

compensatory damages. If they get down to E and they start answering yes or no here, it's not going to make a difference in terms of what they've already done. And, candidly, I don't think it's going to give us any information that will help us in interpreting anything they did.

THE COURT: Let me tell you what information I think it gives us.

If the jury comes back with a Bard verdict in all four categories, and they answer no on question E1, then we will know for purposes of posttrial motions or appeal that it was not the intervening cause that resulted in the jury's verdict. If they answer yes, we'll know that it was, and it becomes an appeal. If we don't ask the question because we don't know whether it is, it becomes an appeal issue.

So it has the potential to simplify posttrial and appeal issues. If they answer one way. If they don't answer the other way, it's as though we didn't ask. That, to me, was the benefit of asking.

The same point on E2. If they give us a number, let's just make one up, $700,000, and we don't know whether or not they reduced it for intervening cause, then we have an appeal issue.

If they tell us we did, we've got the same issue.

If they tell us we didn't, then that issue goes away.

So, again, it offers the possibility of eliminating

12:33:21 an issue on posttrial appeal.

So that's the reason I thought it ought to be included. But now I'm interested in your comments.

MR. STOLLER: Well, I think it emphasizes, a way, -- 12:33:31 in a way it does not, other defenses and issues, that it tells them go back and look again, did you really do this, did you not do this, and emphasizes a defense to the claims in a way that's not true for other things or other elements of the claims.

12:33:45 For example, we don't ask them that question as to assumption of the risk, which is an affirmative defense in -- and I'm not advocating that you add it. But it does -- it highlights things in way for them in a way that we all know, well, at least from our jury observation after the fact, is 12:34:03 that they take these instructions seriously, they take the verdict form seriously, they read them and assume that the things they're asked to do have particular meaning.

And our concern, my concern, is that these questions put particular emphasis on a defense that is obviously 12:34:20 designed to defeat liability and damages in this case.

THE COURT: Okay. I understand that. Thank you.

Defense counsel, your thoughts.

MS. HELM: Your Honor, we have no -- we're comfortable with the verdict form. We don't have anything.

12:34:34 THE COURT: All right.

12:34:35 I understand your point, Mr. Stoller. I think the instructions clearly bring out this defense in any event and so I'm going to leave the verdict form as it is. But your objection is noted.

12:34:46 Counsel, it's 12:35. I think what I'd like to do is suggest that whoever chooses to from each side come back at, say --

Traci, did that hearing get set for today or tomorrow?

12:35:02 THE COURTROOM DEPUTY: 4 o'clock. We have a discovery call at 4:00 o'clock.

THE COURT: -- at 2 o'clock?

MR. NORTH: Sure.

THE COURT: Is that all right? Just to talk about

12:35:08 scheduling issues for the next trial before we lose you all to the road. So let's be back at 2 o'clock, and we'll see you then.

And please leave contact information with Traci so that if we get a question or a verdict we can get in touch

12:35:22 with you quickly.

(Recess taken at 12:35.)

(End of transcript.)

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C E R T I F I C A T E

I, PATRICIA LYONS, do hereby certify that I am duly appointed and qualified to act as Official Court Reporter for the United States District Court for the District of Arizona.

I FURTHER CERTIFY that the foregoing pages constitute a full, true, and accurate transcript of all of that portion of the proceedings contained herein, had in the above-entitled cause on the date specified therein, and that said transcript was prepared under my direction and control, and to the best of my ability.

DATED at Phoenix, Arizona, this 30th day of March, 2018.

s/ Patricia Lyons, RMR, CRR
Official Court Reporter